

From: Kunickis, Sheryl - OSEC

To: Schroeder, Jill; Hill2, Elizabeth - ARS; Chin, Teung; Domesle, Alexander - ARS; Abbott, Linda - OCE; Fajardo,

Julius; Schechtman, Michael; Epstein, David

Subject: Fwd: PPDC Agenda and Materials Date: Friday, October 21, 2016 2:10:54 PM

Attachments: Final Agenda for November 2016 PPDC Meeting.docx

ATT00001.htm

Session 7b ESA Implementation Update.docx ATT00002.htm

Session 7c Epi Framework Update.docx

ATT00003.htm

Session 7d PRIA 4 Update.docx

ATT00004.htm

Session 7e Resistance Management Update.docx

ATT00005.htm

Session 7f Chlorpyrifos Update.docx

ATT00006.htm

Session 7g Glyphosate Update.docx

ATT00007.htm

Looks like a loaded agenda. I can already think of questions for the items listed below! C&T is a topic - could be interesting. DO NOT SHARE this copy. While it will be out, I don't want anyone to say USDA shared it.

Cheers, Sheryl

Sent from my iPad

Begin forwarded message:

From: "Zimmerman, Dea" < Zimmerman. Dea@epa.gov>

Date: October 21, 2016 at 1:59:18 PM EDT

To: Undisclosed recipients:;

Subject: PPDC Agenda and Materials

Dear PPDC Members -

Attached please find the agenda for the November 2-3 PPDC meeting taking place in the first floor conference center in the Potomac Yards South building located at 2777 S. Crystal Drive, Arlington, VA 22202.

Similar to the May 2016, there is a session at 9:00 am on Thursday November 3rd, where OPP managers and staff will be available to discuss questions you may have on selected topics. The session is:

9:00-10:30 7. Question and Answer Session to Topic Updates Sent in Advance of Meeting

Session Chairs: OPP Senior Leadership Team **Session Goal:** Answer guestions from PPDC members on: <!--[if!supportLists]-->a. <!--[endif]--> Acute 6-Pack Testing Alternatives

OPP has prepared summaries for each topic, all of which are attached except the "Acute 6-Pack Testing Alternatives". I will pass this one along by early next week at the latest. Please review these materials in advance of the meeting and come prepared with any questions you may have.

I will also post presentation materials for the rest of the sessions to the PPDC website, hopefully by mid-week, and let you know when that is done.

https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/pesticide-program-dialogue-committee-ppdc

Entering Potomac Yards – please give yourself some extra time.

As a reminder and for those who have never been to Potomac Yards, you will need to go thru security screening to enter the building. You will need to present photo identification to the security guards, sign in and go through the metal scanners. Due to the REAL ID Act, Driver's licenses may not be accepted from **Minnesota**, **Missouri and Washington** (people from these states can use a passport or an official state identification badge). You do not need an escort for the full PPDC meeting happening in the lobby level conference room. I will give the building security guards a list with your name on it to try to expedite your entrance.

If something has come up and you will not be attending the PPDC, please let me know (regrets only). Also please let me know if you will be participating remotely by phone. Safe travels and I look forward to seeing everyone.

Regards,

Dea

Dea Zimmerman
Pesticide Program Dialogue Committee, DFO
<u>Zimmerman.dea@epa.gov</u>
312-353-6344



PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

Lobby Level Conference Center - 2777 Crystal Drive (1 Potomac Yard South), Arlington, VA Conference Line: 1-866-299-3188; Conference Code: 312-353-6344 #

Wednesday, November 2, 2016

9:00-9:20 Welcome and Opening Remarks

Jim Jones, Assistant Administrator, Office of Chemical Safety and Pollution Prevention Jack Housenger, Director, Office of Pesticide Programs

9:20-9:30 Introductions by PPDC Members

9:30-10:30 1. OPP's Role in Agricultural Biotechnology Today and Tomorrow

Session Chair: Robert McNally, Director, Biopesticides and Pollution Prevention Division

Mike Mendelsohn, Senior Regulatory Advisor, BPPD

Elizabeth Milewski, Senior Science Advisor, BPPD

Session Goal: Discuss new technologies for pest control and the role the government, and specifically OPP, will play in ensuring adequate regulation.

9:30-10:00 EPA

10:00-10:30 PPDC Discussion

10:30-10:45 Break

10:45-11:45 2. Zika Update

Session Chair: Arnold E. Layne, Deputy Director, Office of Pesticide Programs Session Goal: Provide an update on OPP's activities since May and discuss regulatory challenges to address the issue of mosquito control.

10:45-11:00 EPA

11:00-11:45 PPDC Discussion

11:45-1:15 Lunch

1:15-2:15 3. Pollinator Protection Updates: Acute Bee Mitigation Proposal and Neonicotinoid Risk Assessment Schedule

Session Chairs: Michael Goodis, Acting Director, Registration Division

Yu-Ting Guilaran, Director, Pesticide Re-evaluation Division

Marietta Echeverria, Chief, Invertebrate-Vertebrate Branch I, Registration Division Session Goal: Provide an update on the acute bee mitigation proposal and the risk assessment schedule for the neonicotinoid active ingredients.

1:15-1:45 EPA

1:45-2:15 PPDC Discussion

2:15-2:45 4. Update from the Pollinator Protection Plan Metrics Workgroup

Session Chair: Michael Goodis, Acting Director, Registration Division

PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING - p. 2

Lobby Level Conference Center - 2777 Crystal Drive (1 Potomac Yard South), Arlington, VA Conference Line: 1-866-299-3188; Conference Code: 312-353-6344 #

Session Goal: Provide the PPDC a current status of this workgroup.

2:15-2:30 EPA

2:30-2:45 PPDC Discussion

2:45-3:00 Break

3:00-3:45 5. Updates on the Certification of Pesticide Applicators Rule and Implementation Activities of the Revised Worker Protection Standard

Session Chair: Kevin Keaney, Chief, Certification and Worker Protection Branch, Field and External Affairs Division

Session Goal: Discuss the Agency's ongoing efforts to protect farmworkers through updates on the progress for implementing the Worker Protection Standard Rule and for finalizing the Certification of Pesticide Applicators Rule.

3:00-3:15 EPA

3:15-3:45 PPDC Discussion

3:45-4:30 6. a. Update on Dicamba Registration

b. Synergy Claims

Session Chair: Dan Kenny, Chief, Herbicide Branch, Registration Division Session Goal: Provide an update on the pending registration of dicamba on herbicide tolerant cotton and soybeans and discuss the implications of synergy patent claims on new registrations.

3:45-4:00 EPA

4:00-4:30 PPDC Discussion

4:45 Meeting Adjourns

PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING - p. 3

Lobby Level Conference Center - 2777 Crystal Drive (1 Potomac Yard South), Arlington, VA Conference Line: 1-866-299-3188; Conference Code: 312-353-6344 #

Thursday, November 3, 2016

9:00-10:30 7. Question and Answer Session to Topic Updates Sent in Advance of Meeting

Session Chairs: OPP Senior Leadership Team

Session Goal: Answer questions from PPDC members on:

- a. Acute 6-Pack Testing Alternatives
- b. Endangered Species Act Implementation Update
- c. Epidemiological Framework
- d. Pesticide Registration Improvement Act (PRIA) 4
- e. Resistance Management
- f. Chlorpyrifos
- g. Glyphosate

10:30-10:45 Break

10:45-11:15 8. Update from the Pesticide Incidents Workgroup

Session Chair: Jackie Mosby, Director, Field and External Affairs Division

Session Goal: Provide an update on accomplishments since May.

10:45-11:00 EPA

11:00-11:15 PPDC Discussion

11:15-11:45 9. Discussion of Agenda Topics for Next Meeting

Session Chair: Jack Housenger, Director, Office of Pesticide Programs Session Goal: Discuss topic areas where PPDC members or OPP feels would be beneficial to have on the next agenda.

11:45-12:00 Public Comment

12:00 Meeting Adjourns

ENDANGERED SPECIES ACT (ESA) IMPLEMENTATION UPDATE PPDC Meeting Nov. 2, 2016 – Session 7b

- Based on recommendations from the 2013 National Academy of Sciences' report "Assessing Risks
 to Endangered and Threatened Species from Pesticides" EPA has been working closely with the
 U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) (collectively
 referred to as the Services) to develop shared interim scientific methods for use in pesticide
 consultations.
- EPA released draft Biological Evaluations (BEs) for three pilot chemicals including chlorpyrifos, diazinon, and malathion in April 2016. Following a 60-day public comment, EPA received over 78,600 comments with about 120 substantive comments meriting detailed review.
- In June 2016, EPA and Services held a two-day meeting that provided a forum for stakeholder suggestions for refining some of the interim scientific methods used in the April 2016 draft BEs. The meeting included opening and closing plenary sessions and breakout sessions intended to address inter-agency developed charge questions related to potential refinements for aquatic modeling, spatial and non-spatial refinements to Step 2 (i.e., EPA's determination of "likely to adversely affect" or "not likely to adversely affect"), and refinements to the weight-of-evidence (WoE) approach for plants and animals. Meeting materials including the agenda, charge questions, the opening plenary presentations, and the closing plenary reports are available at: https://www.epa.gov/endangered-species/5th-esa-workshop-joint-interim-approaches-nas-recommendations. EPA and the Services have reviewed the recommendations and identified those that can be addressed in the short-, mid-, and long-term.
- Recommendations from the June 2016 stakeholder meeting and public comments on the draft BEs for the three pilot chemicals will be addressed in a phased approach, given consultation deadlines and existing resources.
- In September 2016, EPA and the Services held a 3-day workshop to continue work on interim methods and tools for use in Step 3 (i.e., the Services' determination of "jeopardy/adverse modification" or "no jeopardy/no adverse modification" in the BiOp).
- Final BEs for the three pilot chemicals are expected to be released in mid-January 2017.
 - Although this date is one month later than originally anticipated, the January 2017 release
 of the final BEs will not impact the Services draft Biological Opinion (BiOp) deadline, given
 that EPA will provide the Services with any additional data needs in sufficient time for
 integration into the draft BiOp.
 - Expected revisions to the final BEs based on stakeholder feedback will include refined aquatic modeling, error corrections, improved transparency specifically related to the Terrestrial Effects Determination (TED) tool and the WoE matrices, and additions/deletions to the list of endangered and threatened species.
 - Other comments being considered for future BEs include: reducing the size and complexity of the BEs, moving toward more probabilistic approaches, exploring ways to better screen species with little or no risk while still being protective, refining species range maps and potential use sites, exploring use of watershed-level aquatic models, and considering the timing of potential exposure (e.g., linkage with life-history variables) and potential durations of exposure.
- Draft BEs for carbaryl and methomyl are expected to be released for public comment in the spring of 2017.
- The Services expect to release draft BiOps for the three pilot chemicals for public comment in the spring of 2017 with final BiOps by December 2017. Final BiOps for methomyl and carbaryl will be released in December 2018.

Draft "Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment" PPDC Meeting Nov. 2, 2016 – Session 7c

In 2010, OPP developed a draft "Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment" which provides the foundation for evaluating multiple lines of scientific evidence in the context of the understanding of the adverse outcome pathway (or mode of action (U.S. EPA, 2010). The draft framework, which includes two key components: problem formulation and use of the Mode Mode Of Action/Adverse Outcome Pathway (MOA/AOP) frameworks, was reviewed favorably by the SAP in 2010 (FIFRA SAP, 2010).

OPP's draft framework is consistent with updates to the World Health Organization/International Programme on Chemical Safety mode of action/human relevance framework, which highlight the importance of problem formulation and the need to integrate information at different levels of biological organization¹. Consistent with recommendations by the NRC in its 2009 report on *Science and Decisions*², OPP's draft framework describes the importance of using problem formulation at the beginning of a complex scientific analysis. The problem formulation stage starts with planning dialogue with risk managers to identify goals for the analysis and possible risk management strategies. This initial dialogue provides the regulatory context for the scientific analysis and helps define the scope of such an analysis. The problem formulation stage also involves consideration of the available information regarding the pesticide use/usage, toxicological effects of concern and exposure pathways and duration along with key gaps in data or scientific information.

MOA and AOP provide important concepts in this integrative analysis. Both a MOA and an AOP are based on the premise that an adverse effect caused by exposure to a compound can be described by a series of causally linked biological key events that result in an adverse human health or ecological outcome. One of the key components of the Agency's draft framework is the use the MOA framework /AOP concept as a tool for organizing and integrating information from different sources to inform the causal nature of links observed in both experimental and observational studies. Specifically, the modified Bradford Hill Criteria are used to evaluate the experimental support that establishes key events within a mode of action or an adverse outcome pathway, and explicitly considers such concepts as strength, consistency, dose response, temporal concordance and biological plausibility in a weight of evidence analysis.

¹ Meek ME, Boobis A, Cote I, Dellarco V, Fotakis G, Munn S, Seed J, Vickers C. 2014. New developments in the evolution and application of the WHO/IPCS framework on mode of action/species concordance analysis. <u>J Appl Toxicol</u>. 2014 Jan;34(1):1-18.

² NRC (National Research Council). (2009). Science and decisions: Advancing risk assessment. Washington, DC: The National Academies Press. http://www.nap.edu/openbook.php?record_id=12209

One of the recommendations of the SAP was to gain experience integrating epidemiology and human incident information into risk assessment in order to further refine the approach in the draft framework. Consistent with this recommendation, OPP did not finalize the draft framework after the 2010 SAP but instead has used in draft framework in several chemical risk assessments (atrazine, chlorpyrifos and other organophosphates, glyphosate) to gain experience. Through this experience, OPP has refined the proposed approach with an improved, more transparent grading system for epidemiology studies; the revised framework will include this grading system.

In recent years, the <u>National Academies' National Research Council (NRC)</u> has encouraged the agency to move towards systematic review processes to enhance the transparency of scientific literature reviews that support chemical-specific risk assessments to inform regulatory decision making³. The NRC defines systematic review as "a scientific investigation that focuses on a specific question and uses explicit, pre-specified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies". OPP has been collaborating across the other offices in the Office of Chemical Safety and Pollution Prevention (OCSPP) to implement systematic review. The concepts associated with fit-for-purpose systematic review such as standard methods for collecting, evaluating and integrating the scientific data will also be included in the revised, final framework.

OPP is actively working on revising and finalizing the draft framework and anticipates release of the final document within the next few months.

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³ NRC 2011. "Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde"; NRC 2014. "Review of EPA's Integrated Risk Information System (IRIS) Process"

Draft "Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment" PPDC Meeting Nov. 2, 2016 – Session 7c

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OPP is actively working on revising and finalizing the draft framework and anticipates release of the final document within the next few months.

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³ NRC 2011. "Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde"; NRC 2014. "Review of EPA's Integrated Risk Information System (IRIS) Process"

Update on Changes to Maintenance Fees and PRIA 4 PPDC Meeting Nov. 2, 2016 – Session 7d

[These bullets reflect the status of PRIA 4 while we were providing technical advice to the PRIA Stakeholder Coalition during development, but we have not seen the actual Bill language being developed by Congress.]

Maintenance Fees

- Extends fees for 7 more years from FY'17 thru FY'23;
- Fees increased from \$27.8M to \$31.0M per year;
- Can average across years to correct for over or under collection in previous years during PRIA 4;
- Eliminates IT set-aside (\$800,000 per year) to improve (a) electronic tracking of registration submissions, (b) electronic tracking of conditional registrations, (c) electronic review of labels, (d) electronic CSFs and (e) ESA database enhancements (but reporting on the unspent balance of PRIA 3 IT set-asides remains);
- Creates new \$500,000 per year set-aside to support efficacy guideline development and rulemaking for invertebrate pests of significant public health and/or economic importance with a mandatory schedule of deliverables;
- Creates new \$500,000 per year set-aside to support GLP inspections;

PRIA 4 (Pesticide Registration Enhancement Act of 2016)

- Extends PRIA for 7 more years from FY'17 thru FY'23;
- Increases the number of covered fee categories from 189 to 212; changes include but not limited to:
 - adds harmonization with Codex MRLs to existing category;
 - adds categories for pests requiring efficacy data and review;
 - adds new EUP categories for AD, BPPD and RD chemicals;
 - AD categories modified to be consistent with 158W;
 - adds unregistered source of AI category for BPPD;
 - adds new PIP categories;

- adds new inert safener categories and lengthens certain inert category timeframes where warranted by their average completion times and the # of renegotiations;
- Enhances incentives for reduced-risk submissions by raising fees for the corresponding non-reduced risk categories (new conventional AIs and new uses);
- Eliminates small business waivers for Gold Seal letters;
- New reporting requirements:
 - identify reforms to streamline new AI and new use processes and provide prompt feedback to applicants during the process;
 - progress in meeting mandatory schedule in developing efficacy guidelines for invertebrate pests of significant public health and/or economic importance;
 - # of GLP inspections/audits conducted;
 - progress in priority review and approval of new pesticides to control vector borne pests in the U.S. including territories and military bases globally;
 - # of registration review cases completed, fully implemented, required mitigation
- Updates Section 5 on EUPs to be consistent with PRIA 4 timeframes.

EPA's Pesticide Registration Notices (PRNs) on Resistance Management PPDC Meeting Nov. 2, 2016 – Session 7e

Background

Many pesticides have gradually lost their effectiveness over time because pests have developed resistance, a significant decrease in sensitivity to a pesticide, which reduces the field performance of these pesticides. The agency is concerned about resistance issues and believes that managing the development of pesticide resistance, in conjunction with alternative pest-management strategies and Integrated Pest Management (IPM) programs, is an important part of sustainable pest management. To address the growing issue of resistance and prolong the useful life of pesticides, the agency has initiated a more widespread effort that is aimed at combating and slowing the development of pesticide resistance. On June 3, 2016, the agency concurrently released and requested public comment on two draft Pesticide Registration Notices (PRNs) related to pesticide resistance. The public comment closed on September 1, 2016. The two PRNs include:

- 1. PRN 2016-X: Draft Guidance for Pesticide Registrants on Pesticide Resistance

 Management Labeling. PRN 2016-X revises and updates PRN 2001-5, which is the
 agency's current guidance for pesticide resistance management labeling. This PRN
 applies to all agricultural pesticides except plant-incorporated protectants (PIPs), which
 are covered by a separate guidance issued by the Biopesticides and Pollution Prevention
 Division (BPPD). The updates in PRN 2016-X focus on pesticide labels and are aimed at
 improving information about how pesticide users can minimize and manage pest
 resistance.
- 2. PRN 2016-XX: Draft Guidance for Pesticide Registrants on Herbicide Resistance Management Labeling, Education, Training, and Stewardship. PRN 2016-XX applies only to herbicides. This PRN communicates the Agency's current thinking and proposes an approach to address herbicide-resistant weeds by providing guidance on labeling, education, training, and stewardship for herbicides undergoing registration review or registration. It is part of a holistic, proactive approach to slow the development and spread of herbicide-resistant weeds, and to prolong the useful lifespan of herbicides and related technology. The Agency is focusing on guidance for herbicides first because they are the most widely used agricultural chemicals, no new herbicide mechanism of action has been developed in the last 30 years, and the number of herbicide-resistant weed species and acres infested with resistant weeds have increased rapidly in recent years.

Current Status

The Agency is in the process of reviewing and addressing the public comments we received on these PRNs.

- 1. The Agency received 19 comment letters on the pesticide labeling PRN (2016-X) from non-governmental organizations (NGOs), grower groups, professional scientific societies, registrants, resistance action committees (RACs), and USDA. The main themes included the following:
 - A. General agreement that additional information on resistance management on labels would be useful especially the routine inclusion of a pesticide's Mode of Action group as set by the various RACs.
 - B. A few RACs disagreed with some of the suggested label statements in the guidance, particularly for fungicides and insecticides. EPA is in the process of evaluating if and how these label statements should be altered based on these comments.
 - C. Some commenters expressed concern and confusion on: (1) whether non-agricultural pesticides are covered and (2) whether all of the guidance in this PRN is mandatory for registrants or pesticide users. EPA is in the process of reviewing these comments and will clarify these issues in the final version of the PRN.
- 2. The Agency received 27 comment letters on the herbicide resistance management PRN (2016-XX) from NGOs, crop groups, professional societies, registrants, RACs, and USDA. The main themes included the following:
 - A. General agreement that pesticide labels should provide additional resistance management information. A few commenters, however, did not agree that extensive resistance management language is appropriate for labels.
 - B. The Agency proposed three categories of concern (low, medium, high) based on the potential for weeds to develop herbicide resistance. The three categories proposed different approaches for resistance management in regards to labeling, education, training, and stewardship guidance. Most commenters recommended that all herbicides be grouped into a single category and treated as if there is high concern for resistance.
 - C. Many commenters were against having the registrants provide additional information to the user/grower (e.g. a separate lists of resistant weeds, additional reporting of resistant weeds, or resistance management plans).

Next Steps

The Agency is evaluating the public comments and expects to finalize both PRNs in late 2016. Also, the Agency plans to implement herbicide resistance measures for existing chemicals during registration review, and to implement herbicide resistance measures for new herbicides and new uses at the time of registration.

Chlorpyrifos Status Update for PPDC Meeting Nov. 2, 2016 – Session 7f Prepared: October 19, 2016

Background

The EPA must respond to a National Resources Defense Council (NRDC) and Pesticide Action Network of North America (PANNA) petition seeking the revocation of all chlorpyrifos tolerances and cancelation of all registrations for chlorpyrifos, citing human health concerns. In October 2015, the EPA issued a proposed tolerance revocation for chlorpyrifos based on the science as it stood. There are several unresolved scientific issues the EPA has been working through before issuing a final decision.

EPA has considered several approaches in determining the critical effect, and related uncertainties, for use in the chlorpyrifos human health risk assessment. The 2014 revised human health risk assessment used dose-response data on acetylcholinesterase inhibition (AChI) in laboratory animals to derive a point of departure. However, the EPA believes that evidence from epidemiology studies indicates effects may occur at lower exposures than indicated by the toxicology database. The EPA consulted with the FIFRA Scientific Advisory Panel (SAP) on using a specific epidemiology study to establish a new toxicological endpoint and associated point of departure for the chlorpyrifos risk assessment. The SAP advised against that approach. The SAP also emphasized concern that the point of departure based on AChI is not sufficiently health protective for use in risk assessment. The 2016 SAP cited that epidemiology and toxicology studies suggest there is evidence for adverse health outcomes associated with chlorpyrifos exposures below these levels, which is consistent with recommendations from the 2012 SAP meeting on chlorpyrifos.

The EPA has thoroughly considered the SAP's recommendations, and is currently finalizing its 2016 revised risk assessment. The EPA anticipates making the revised risk assessment, along with an updated drinking water assessment, available for public comment in the very near future. The EPA anticipates issuing a final tolerance rule for chlorpyrifos by the court-ordered deadline, March 31, 2017.

Milestones

- The EPA anticipates issuing a Notice of Data Availability (NODA) for the proposed rule in the very near future. The NODA will include a revised human health risk assessment, updated drinking water assessment, and other supporting information. The EPA will also notify the World Trade Organization of EPA's impending tolerance decision at this time.
- The Notice of Data Availability will be published for a 60-day public comment period.
- The EPA will respond to public comments and finalize its decision on the chlorpyrifos tolerance rule by March 31, 2017.

Glyphosate Update PPDC Meeting Nov. 2, 2016 – Session 7g

Overview

Glyphosate is a non-selective, phosphonomethyl amino acid herbicide registered to control weeds in various agricultural and non-agricultural settings. Labeled uses of glyphosate include over 100 terrestrial food crops as well as other non-agricultural sites, such as greenhouses, aquatic areas, and residential areas. Use of glyphosate in the United States and globally has increased overtime, particularly with the introduction of glyphosate-resistant crops; however, usage has stabilized in recent years due to the increased number of weed species becoming resistant to glyphosate. Glyphosate is currently undergoing Registration Review, which reviews all registered pesticides at least every 15 years as mandated by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Recently, EPA collected and analyzed a substantial amount of data informing the carcinogenic potential of glyphosate and utilized the draft "Framework for Incorporating Human Epidemiological & Incident Data in Health Risk Assessment", which provides the foundation for evaluating multiple lines of scientific evidence. A comprehensive analysis of data on glyphosate from submitted guideline studies and the open literature was performed. This includes epidemiological, animal carcinogenicity, genotoxicity, and absorption, distribution, metabolism, and excretion (ADME) studies. Guideline studies were collected for consideration from the toxicological databases for glyphosate and glyphosate salts. A fit-for-purpose systematic review was executed to obtain relevant and appropriate guideline and open literature studies with the potential to inform the human carcinogenic potential of glyphosate. Furthermore, the list of studies obtained from the toxicological databases and systematic review was cross-referenced with recent internal reviews, review articles from the open literature, and international agency evaluations.

Available data from epidemiological, animal carcinogenicity, and genotoxicity studies were reviewed and evaluated for study quality and results to inform the human carcinogenic potential of glyphosate according to the 2005 Guidelines for Carcinogen Risk Assessment. A total of 58 epidemiological studies, 20 animal carcinogenicity studies, and almost 200 genotoxicity assays were considered in the current evaluation. Additionally, multiple lines of evidence were integrated in a weight-of-evidence analysis using the modified Bradford Hill Criteria considering concepts, such as strength, consistency, dose response, temporal concordance, and biological plausibility. The totality of the data has been used by the agency to inform cancer classification descriptors according to the 2005 Guidelines for Carcinogen Risk Assessment. The agency originally planned to hold the FIFRA Scientific Advisory Panel (SAP) evaluation of human carcinogenic potential for the active ingredient glyphosate on October 18-21, 2016.

On October 14, 2016, EPA postponed the FIFRA SAP meeting due to recent changes in the availability of experts for the peer review panel. Given the importance of epidemiology in the review of glyphosate's carcinogenic potential, the agency believes that additional expertise in epidemiology will benefit the panel and allow for a more robust review of the data. As a result, the SAP meeting on glyphosate has been postponed. The agency will issue another announcement once the new date for the SAP meeting on glyphosate has been determined.

From: Kunickis, Sheryl - OSEC

To: Mueller, Rick - NASS; Chin, Teung; Schroeder, Jill; Epstein, David; Fajardo, Julius; Domesle, Alexander - ARS

Subject: FW: June ESA stakeholder workshop: complete meeting materials

Date:Tuesday, June 28, 2016 3:58:18 PMAttachments:workshop reading materials.final.docxWOE charge questions.final.docx

aquatic modeling charge questions.final.docx refinements charge questions.final.docx

workshop final agenda.docx Capel et al 2001.pdf

See attached as they are the final versions – fyi.

From: Nguyen, Khue [mailto:Nguyen.Khue@epa.gov]

Sent: Monday, June 27, 2016 11:32 AM

To: Patrice Ashfield; craig_aubrey@fws.gov; Cowles, James; Brett Hartl; Kunickis, Sheryl - OSEC; Pease,

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Subject: June ESA stakeholder workshop: complete meeting materials

Hi all,

I am forwarding to the workshop "floaters" the complete meeting materials for the June ESA stakeholder workshop, which includes the final agenda, the charge questions for each breakout group, and the list of reading materials.

See you all at the workshop on Wednesday!

Thanks,

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ESA STAKEHOLDER WORKSHOP (JUNE 29 – 30, 2016) RECOMMENDED READING MATERIALS

Materials to read prior to the workshop All of the draft biological evaluation documents can be accessed from the following EPA website (Implementing NAS Report Recommendations on Ecological Risk Assessment for Endangered and Threatened Species): https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and.

All Breakout Sessions:

- The NAS Report (Assessing Risk to Endangered and Threatened Species from Pesticides): General Conclusions and Recommendations (pages 33-34)
- Relevant sections of EPA OPP Ecological Risk Assessment for Pesticides
 (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/ecological-risk-assessment-pesticides-technical)
- For an understanding of ESA Consultation, https://www.fws.gov/endangered/what-we-do/fag.html#9

Breakout Session: Improving Aquatic Modeling: Changes to conceptual and mathematical approaches incorporated into Bins 3 and 4 (flowing waters) and Evaluating watershed model results

Both aquatic modeling breakout groups:

- Attachment 3-1, Background document: Aquatic Exposure Estimation for Endangered Species
- The NAS Report (Assessing Risk to Endangered and Threatened Species from Pesticides):
 Section 3
- Capel et al. 2001. The behavior of 39 pesticides in surface waters as a function of scale. Hyrol. Process. (15) 1251-1269 (see attached).

Breakout Session: Refinements to Steps 1 and 2: (Ideas for 'streamlining' and/or improving the analyses used to make effects determinations in future BEs):

Breakout Group: REFINEMENTS 1 (Refinements to Steps 1 and 2: Spatial analysis):

- Draft Chlorpyrifos Problem Formulation for ESA Assessment (Chapter 1) especially section
 1 A 1
- Attachment 1-2 CDL Crosswalk
- Attachment 1-3 Method for Establishing the Use Footprint
- Attachment 1-6 Co-Occurrence Analysis
- Appendix 1-6 Use Site, General Land Cover Class, and HUC2 Matrix for Chlorpyrifos
- Draft Chlorpyrifos Effects Determinations for ESA Assessment (**Chapter 4**) especially sections 2, 3, and 4
- Appendix 4-7 Refined Risk Analyses for 11 Listed Birds Exposed to Diazinon especially section

- Appendix 4-7-supp-2 GAP Land covers assigned as preferred habitats (diazinon)
- NAS Report (2013; Assessing Risk to Endangered and Threatened Species from Pesticides):
 Geospatial Data for Habitat Delineation and Exposure Modeling, pages 41-48; Section 3
 Conclusions and Recommendations, pages 58-59

Breakout Group: REFINEMENTS 2 (Refinements to Steps 1 and 2: Non-spatial analysis):

- Draft Chlorpyrifos Problem Formulation for ESA Assessment (**Chapter 1**) for question 3b, especially sections 1.4.1 and 1.4.2
- Draft Chlorpyrifos Effects Determinations for ESA Assessment (**Chapter 4**) especially sections 7-2 and 7-3
- Attachment 1-4 Process for Determining Effects Thresholds
- Attachment 1-5 Method for Deriving Species Sensitivity Distributions for Use in Pesticide Effects Determinations for Listed Species
- Attachment 1-7 Methodology for Estimating Exposures to Terrestrial Animals
- Attachment 3-1 Background Document: Aquatic Exposure Estimation for Endangered Species
- NAS Report (2013; Assessing Risks to Endangered and Threatened Species from Pesticides) especially Chapter 5
- Draft Chlorpyrifos Effects Characterization for ESA Assessment Chapter 2

Breakout Sessions: Weight of Evidence for Listed Animals and Plants

Both Weight of Evidence breakout groups (animals and plants):

- Draft Chlorpyrifos Problem Formulation for ESA Assessment (**Chapter 1**) especially section 1.4.2
- Attachment 1-4 Process for Determining Effects Thresholds
- Attachment 1-5 Method for Deriving Species Sensitivity Distributions for Use in Pesticide Effects Determinations for Listed Species
- Attachment 1-7 Method for Estimating Exposure to Terrestrial Animals
- Attachment 1-8 Review of Open Literature Toxicity Studies for Pilot Chemical Biological Evaluations
- Attachment 1-9 Applying a Weight-of-Evidence Approach to Support Step 2 Effect
 Determinations, i.e., Not Likely to Adversely Affect (NLAA) or Likely to Adversely Affect (LAA)
- Attachments 1-11 through 1-21 Biological Information on Listed Species
- Attachment 3-1 Background Document: Aquatic Exposure Estimation for Endangered Species
- NAS Report (2013; Assessing Risks to Endangered and Threatened Species from Pesticides) especially the Chapter 2 section on Best Data Available (beginning on page 39), Chapters 3 and 4 sections on uncertainties, and Chapter 5 section on probabilistic approach
- Draft Chlorpyrifos Effects Characterization for ESA Assessment (Chapter 2)
 - Draft Chlorpyrifos Exposure Characterization for ESA Assessment (Chapter 3)

Supplemental reading materials for both WOE Groups:

- As referenced by the NAS Panel report:
 - Exponent (Bellevue, Washington), for Science Advisory Board for Contaminated Sites in British Columbia. Guidance for a weight of evidence approach in conducting detailed ecological risk assessments (DERA) in British Columbia. Prepared for the British Columbia

Ministry of Environment, June 2010 (Available here: http://www.sabcs.chem.uvic.ca/a%20January%202011%20Posting%20copy%20Weight %20of%20Evidence%20Final%201.pdf)

 Igor Linkov, Drew Loney, Susan Cormier, F. Kyle Satterstrom and Todd Bridges. Review: Weight-of-evidence evaluation in environmental assessment: Review of qualitative and quantitative approaches. Science of the Total Environment 407: 5199–5205, 2009. (Available at no cost from Google Scholar)

• Additional suggestion:

 Bruce K. Hope and Jacquelyn R. Clarkson. A strategy for using weight-of-evidence methods in ecological risk assessments. Human and Ecological Risk Assessment 20: 290– 315, 2014. (Copyrighted)

ESA STAKEHOLDER WORKSHOP (JUNE 29 – 30, 2016):

Breakout Sessions WOE 1 and WOE 2: Weight of Evidence for Listed Animals and Plants

The draft biological evaluations for chlorpyrifos, diazinon and malathion rely upon a weight of evidence (WoE) approach to make species-specific effects determinations. Risk conclusions are based on the integration of exposure and effects information relevant to an individual of a listed species, as well as life history characteristics that may influence exposure or indirect effects (e.g., diet). Different types of effects are identified in this approach as separate lines of evidence; including: mortality, growth, reproduction, behavior, sensory effects and indirect effects. Additionally, other factors that could affect the magnitude of both direct and indirect effects (e.g., chemical or abiotic stressors) are evaluated as lines of evidence. Weighting is applied to each line of evidence and the weighting criteria provide guidelines for supporting effects determinations based on the pairings of risk and confidence. The current weighting criteria are defined in Attachment 1-9.

An effort was made to incorporate and evaluate as much toxicity and exposure data as possible to determine whether adverse effects are anticipated from the effects of the action. Both the toxicity and exposure information are evaluated to determine the risk and confidence associated with each line of evidence. Currently, the process uses numeric thresholds to determine risk. EPA and the services have discussed integrating distributions of effects and exposures to move towards a more probabilistic approach (e.g., such as the method used in the Terrestrial Investigation Model); however, this is seen as more of a long term goal for application to all species. EPA and the Services are interested in suggestions that improve the WoE method. When addressing the questions below, answers will be grouped into "short term" or "long term" solutions, considering the magnitude of work associated with developing and applying the methods to all listed species ($n \approx 1800$).

The same set of questions will be considered by the WoE groups focused on plants and on animals; however, the discussions are expected to differ. For instance, issues related to exposure differ between animals and plants in that the routes and models are conceptually and mathematically different. For effects, data are available for multiple lines of evidence for assessing direct effects to animals (i.e., mortality, growth, reproduction, behavior and sensory); whereas mortality, growth and reproduction data are only available for plants. It is expected that discussions related to animals will likely surround the topics of assessing direct effects to listed individuals as well as indirect effects due to impacts on animals and plants. For plants, discussions should probably focus more on indirect effects due to impacts to animals upon which they depend (e.g., for pollination or seed dispersal).

- Exposure Information Criteria used to assess exposure estimates ultimately answer the
 question, "how confident are we that exposure estimates represent environmental
 concentrations that could occur based on allowable labeled use?" The current approach for
 characterizing exposure considers the <u>relevance</u> of predicted EECs for species' habitats and the
 robustness of EECs derived from environmental fate models (see Attachment 1-9 for more
 details). Considering the current approach to characterizing exposure:
 - o **CHARGE QUESTION 1**: Comment on/suggest alternative methods for presenting exposure information (e.g., probability distributions, consideration of a range of exposure estimates, consideration of duration of exposure) and how the information can be weighed for each line of evidence's risk conclusion.
 - CHARGE QUESTION 2: Comment on the criteria used to weight Confidence in the estimation of exposure as described in Supplemental Information to Attachment 1-9.

- Effects Information- Similar to the exposure characterization, the effects data are evaluated to answer the question, "how confident are we that available toxicity data will accurately predict an effect to the listed species?" The current approach considers 1) biological relevance- whether there is an established relationship between the measure of effect and the assessment endpoint, 2) relevance of surrogate- how representative the tested organisms used in the toxicity studies are at informing the potential for adverse effects to listed species or critical habitat, and 3) robustness- whether there is consistency within the line of evidence for the taxonomic grouping of interest (see Attachment 1-9 for more details). Considering the current approach to characterizing effects:
 - CHARGE QUESTION 3: Comment on approaches for incorporating data quality into the weight assigned to a line of evidence. The current approach to data quality is described in Attachment 1-8.
 - CHARGE QUESTION 4a: For animals, to what extent can taxa with robust data sets be used as surrogates for other taxonomic groupings where lines of evidence have little or no data (e.g., mammals for reptiles)?
 - O **CHARGE QUESTION 4b**: For plants, comment on the approach to surrogacy. Is there a better or more representative way to group species?
 - CHARGE QUESTION 5: How can we more effectively incorporate the breadth of the available toxicity information (*i.e.*, not just the most sensitive endpoints), including magnitude of effect, into the characterization of effects and weight of evidence?
 - CHARGE QUESTION 6: How can we effectively weigh the impacts of other stressors (e.g., temperature) on the LAA/NLAA call, especially in the event of little or no data? CHARGE QUESTION 7: Are there additional sublethal effects that have an established relationship with an assessment endpoint that should be considered as lines of evidence?
 - CHARGE QUESTION 8: Comment on the criteria used to weight Confidence in the estimation of effects as described in Supplemental Information to Attachment 1-9.
- <u>Risk Estimation</u>- Risk is established by comparing the overlap of exposure with effect levels from available toxicity studies for each line of evidence. Consideration is given to the degree of overlap between exposure and effects data. Considering the current approach to estimating risk:
 - CHARGE QUESTION 9: Comment on the criteria used to weight Risk as described in Supplemental Information to Attachment 1-9.

ESA STAKEHOLDER WORKSHOP (JUNE 29-30, 2016):

Breakout Sessions: Improving Aquatic Modeling

Breakout Session AQUATIC 1: Changes to Conceptual Models and Mathematical Approaches Incorporated into Bins 3 and 4 (Flowing Waters):

In the draft Biological Evaluations (BEs), effect determinations are made at the individual scale of biological organization. Consequently, the goal is to accurately predict maximum pesticide concentrations that may occur in different aquatic habitats utilized by listed species and are spatially and temporally relevant to the listed species. The modeling approach presented in the draft BEs leveraged EPA's current generic aquatic modeling approach by using the Pesticide in Water Calculator (PWC) shell, a combination of field-scale models (PRZM5/VVWM), to generate estimated exposure concentrations (EECs) for three generic flowing water bins of varying volumes and flow rates (Bins 2, 3, and 4). The Bin 2 estimates are intended to represent lower-flow habitats, such as first-order streams. When considered in relation to field-scale monitoring data, such as those obtained from edge-of-field (EOF) studies, model results should provide confidence in EECs for this bin. There is expected to be less confidence in applying this approach for deriving estimates for Bins 3 and 4, because processes that affect larger-scale concentration dynamics (e.g., longitudinal dispersion) are not accounted for. The EECs derived for these higher-flow habitats in the draft BEs are extremely high and seem to defy both professional judgement and typical patterns seen in contaminant monitoring data.

In the context of watershed hydrodynamics, the three flowing bins represent aquatic habitats which would ideally be representative, for example, of streams that are sequentially connected within a watershed. While runoff and drift from a field adjacent to a Bin 3 and/or 4 waterbody can directly contribute loading, the EECs generated from these types of events are being characterized with Bin 2 EECs, as these EECs may be reflective of concentrations occurring before complete mixing within the Bin 3 and/or 4 waterbody had occurred. Initial modeling generated Bin 3 and 4 EECs that exceed those generated for Bin 2, which runs counter to expectations based on standard transport dynamics, *e.g.*, dispersive dampening of chemographic peak maxima as a pulse of contaminant moves downstream. Given the apparently unreasonably high EECs for Bins 3 and 4, a qualitative approach was considered in the draft BEs for use in assessing these bins. The approach relied on monitoring data to demonstrate a downward trend in the magnitude of peak exposures. Consistent with published studies showing a reduction in exposures as one moves down a watershed network, the approach showed a 5-fold reduction in exposure from Bin 3-like streams and a 10-fold reduction from Bin 3-like streams to Bin 4-like streams. The draft BE also applied a qualitative comparison of volumes and flowrates to suggest a reasonably conservative magnitude of exposure expected in Bins 3 and 4 as a separate line of evidence.

Charge Questions:

- 1. EPA explored several factors in using the PWC, including incorporation of a baseflow and use of the daily average instead of the instantaneous peak EEC. What are the strengths and weaknesses of these modifications? Are there other modifications that can be made and what are their strengths and weaknesses?
- 2. How appropriate are the methods used in the draft BEs to develop field/watershed sizes and waterbody lengths for these Bins? What reasonable alternatives could be used to model

- watershed processes that allow for accurate estimation of possible exposure concentrations (including the maximum) in these flowing bins based on product labeling?
- 3. For the bins (3 and 4) that represent larger flowing systems, what ways of incorporating the effects of dispersive mixing and/or peak desynchronization into concentration estimates are reasonable?
- 4. What are the strengths and weaknesses of alternative mechanistic or regression-based watershed models such as the Soil and Watershed Assessment Tool (SWAT), the Hydrological Simulation Program-Fortran (HSPF) and the Watershed Regressions for Pesticides (WARP) for simulating aquatic pesticide concentrations at the temporal resolution and national scales required for ESA assessment? Are there other watershed models that should be considered?
- 5. What is the desired and appropriate spatial scale for EECs for Bins 3 and 4? Specific PWC EECs were developed for HUC2 regions. Can or should the EECs for Bins 3 and 4 be at a finer spatial scale given a nationwide consultation?

Breakout Session AQUATIC 2: Evaluating Watershed Model Results:

In the Draft BEs, EPA employed an approach for flowing waters in an effort to approximate watershed processes. Regardless of the model employed, the EECs from any model need to be conservative (*i.e.*, protective of the species of concern) and scientifically defensible in order to be used for risk assessment purposes. Typically, for EPA's use of PRZM5/VVWM as a field-scale model for vulnerable waters (*e.g.*, headwater streams), this would be done by comparing model outputs to field monitoring data (*i.e.*, edge of field runoff studies), where pesticide monitoring data is associated with pesticide-applications under well-described conditions (*i.e.*, application rates, field characteristics, water characteristics, and meteorological conditions). However, for watershed modeling, which aggregates exposure across a larger area, field-scale monitoring data, and the associated well-described conditions for all locations in the watershed, can be extremely difficult to obtain and, as a watershed model aggregates exposure, it may not be necessary.

Available literature documents have evaluated watershed models, including the NAS-recommended model SWAT, using general and targeted watershed monitoring data that is focused on known high pesticide-use areas, provided the data are collected at a high enough frequency to adequately capture the peak exposure concentration along with variations in concentration in the receiving stream. Unlike field monitoring data, general monitoring data (*i.e.*, sometimes described as ambient monitoring data) often lacks background information on application rates and field conditions and can be problematic when used for comparisons to model-generated EECs. They may, however, provide a lower bound for model-generated EECs. Targeted watershed monitoring (*e.g.*, studies at a watershed scale that are targeted to areas of known high pesticide use, with a sampling frequency targeted to the timing of use and subsequent runoff events) has been proposed as a means to provide more than a lower bound, especially when such monitoring spans multiple years and can be tied to factors that drive pesticide transport from field to water bodies. Such data are used to complement the results from modeling, not as a substitute for modeling.

In the Exposure chapter of the 2013 NAS report¹, the NAS noted that "If pesticides are to be used without jeopardizing the survival of listed species and their habitats, the estimated environmental concentrations (EECs) to which the organisms and their habitats will be exposed need to be determined. Chemical fate and transport models are the chief tools used to accomplish that task." (p. 49) The NAS further went on to describe a stepwise approach to fate and transport modeling, commenting on the use of various models such as AgDRIFT, PRZM, and EXAMS (p. 52-54). The NAS then cautioned that "in evaluating models, general monitoring data and field studies need to be distinguished. General monitoring studies provide information on pesticide concentrations in surface water or ground water on the basis of monitoring of specific locations at specific times. The monitoring reports, however, are not associated with specific applications of pesticides under well-described conditions, such as application rate, field characteristics, water characteristics, and meteorological conditions. General monitoring data cannot be used to estimate pesticide concentrations after a pesticide application or to evaluate the performance of fate and transport models." (p. 54) Though not as abundant as general monitoring data, field-scale monitoring studies are available for many pesticides, including the three OPs. However, monitoring data with this type of supporting information are generally lacking at the watershed scale.

¹ National Academy of Sciences. 2013. Assessing Risks to Endangered and Threatened Species from Pesticides. The National Academies Press. Washington, DC.

Additionally, the general monitoring data, specifically at the watershed scale, sometimes include data sets which are spatially and temporally targeted to varying degrees with pesticide applications. Lastly, the NAS noted that "pesticide fate and transport models do not provide information on the watershed scale; they are intended only to predict pesticide concentrations in bodies of water at the edge of a field on which a pesticide was applied." (p. 54) The NAS also noted that "different hydrodynamic models are required to predict how pesticide loadings immediately below a field are propagated through a watershed or how inputs from multiple fields (or multiple applications) aggregate throughout a watershed." The NAS report did not provide additional discussion on the monitoring data requirements (e.g., metadata such as use rates, location, and timing) needed to evaluate watershed models.

Given the distinctions above between field-scale and watershed-scale models, the question arises "how does one evaluate the results generated from a watershed model?" EPA is proposing to use of the following multiple lines of evidence to evaluate the range of scientifically-defensible EECs for each flowing bin: consideration of available edge-of-field monitoring data and edge-of-field modeled estimates from PRZM5; incorporation of results from multiple watershed models, as appropriate; and consideration of statistical approaches to estimate confidence bounds around general monitoring data that were collected at a greater than a daily time step (*i.e.*, SEAWAVE Q and bias factors).

Charge Questions:

- 1. In what ways are a "multiple lines of evidence" approach appropriate for evaluating the results from a watershed model? What would be the "lines of evidence" and sources of information?
- 2. How can different types of monitoring data be distinguished? What metadata requirements (e.g., use info, sample frequency, etc.) can be used to distinguish types of monitoring data?
- 3. What roles can the various types of monitoring data play in the evaluation of results from a watershed model (e.g., general monitoring doesn't predict maximum but has other roles)?
- 4. What other approaches are available for evaluating results from watershed models?
- 5. To what extent can we rely on historical monitoring data when product labeling has changed and application-specific information is lacking?
- 6. Are there new or different types of monitoring that could be employed to further our understanding of aquatic modeling estimates?

ESA STAKEHOLDER WORKSHOP (JUNE 29 – 30, 2016):

Breakout Session: Refinements to Steps 1 and 2 (Ideas for 'streamlining' and/or improving the analyses used to make effects determinations in future BEs)

In accordance with the Endangered Species Act (ESA), the Biological Evaluation (BE) determines whether there is a potential for a single individual of a listed species, or its designated critical habitat, to be adversely affected (directly or indirectly) by a federal agency's proposed action (in this case registering pesticide labels). This is accomplished by first identifying which species ranges/critical habitats overlap with the 'action area' (from the BE Step 1: 'May Affect'/'No Effect' determinations). Once a determination is made for each listed species and critical habitat, species- and critical habitat-specific analyses for all listed resources that have 'May Affect' determinations are conducted to evaluate whether there is a potential for a single individual (or essential critical habitat feature) to be adversely affected² by the use of a pesticide (BE Step 2: 'Likely to Adversely Affect'/Not Likely to Adversely Affect' determinations). Therefore, Step 1 is intended to identify those species/critical habitats that require species-specific analyses (i.e., those that need to proceed to Step 2) and Step 2 is intended to identify the potential for adversely affecting a single individual or critical habitat feature. Key to these processes is the ability to identify areas of overlap among potential use sites, areas of potential effects, and species range/critical habitat areas over the duration of the proposed action (in some cases this may be 15 years or more).

Breakout Group: REFINEMENTS 1 (Refinements to Steps 1 and 2: Spatial analysis):

O For agricultural uses, the interim process identifies potential use sites by collapsing >100 Cropland Data Layer (CDL) classes into 11 agricultural use categories, some of which are unambiguous major crops (corn, cotton, etc.), and some of which are aggregated "minor" crops, e.g., orchards and vineyards, or ground fruit and vegetables. (These minor crops were aggregated to address uncertainties in crop identification in the CDL, and to anticipate future use areas for pesticides, based on current uses.) Therefore, in some cases, specific crop uses are being identified in areas where the specific crop likely does not occur. For example, the orchard-vineyard layer is used for all orchard crops, including citrus. Diazinon is registered for some orchard crops, but not citrus – the spatial analysis is showing orchard use sites for diazinon in Florida – but most of those use sites are likely citrus.

¹ The action area is defined by statue as all areas to be affected directly or indirectly by the Federal Action and not merely the immediate area involved in the Action (50 CFR 402.02). The action area is, thus, related to the proposed action and is independent of the geographic area in which listed resources occur.

² Adverse effects to an individual are not limited to mortality, and include short-term and temporary effects (from direct and/or indirect effects) to individuals. Step 2 analyses do not evaluate the potential for "jeopardy" or "adverse destruction/modification" for species and critical habitat, respectively. Such an analysis would be conducted in Step 3 in a Biological Opinion.

- <u>CHARGE QUESTION 1a</u>: Is there a better way to accurately identify potential agricultural use sites, while still addressing concerns for future use for the duration of the proposed action?
 - Are there some CDL classes that we have more confidence in than others?
 - Is using the Census of Agriculture to eliminate counties where labeled uses do not occur a viable option for both current uses and future uses (within the duration of the proposed action)? If so,
 - O How should we deal with "undisclosed" census values?
 - O Do these data (or other suitable data) reflect "no usage" or "low" levels of usage over the duration of the proposed action?
- O Non-agricultural label uses include a wide range of land cover and land use categories. In the BEs, each label use is considered and represented by the best available land cover data. Generally, the National Land Cover Dataset (NLCD) is used to represent non-agricultural label uses. When the NLCD is inadequate, other data sources are used as appropriate.
 - <u>CHARGE QUESTION 2a</u>: Is there a better way to accurately identify potential non-agricultural use sites, while still addressing concerns for future use for the duration of the proposed action?
 - Are there additional data not considered in the BEs that may be useful for geographically identifying non-agricultural use sites?
 - Are there surrogate data (those that could be used to help inform potential use sites) that could be used for non-ag categories that we have not considered?
- O Some uses do not have clear geographic boundaries (*i.e.*, they are difficult to limit geographically via label language). For some chemicals, this can result in an action area that encompasses the entire US and its territories.
 - <u>CHARGE QUESTION 3a</u>: How can we better identify potential use sites for pesticide uses that do not have clear geographic boundaries? How could these potential use sites be better identified spatially?
 - Could a process to modify labels (to clarify potential use sites) be developed during the BE process? If so, what would that process look like?
 - o For example, when in the BE process would label clarifications be most useful? Could label modifications be in the form of a registrant commitment to modify a label as part of the final decision? How could Bulletins Live Two be best used in the process?

- For uses such as mosquito adulticide use, what other information could be pulled in to the analyses to help accurately limit the spatial extent (for example census information, or protected/managed lands) for the duration of the proposed action? Is there a human population density threshold where the cost of applying a pesticide would be too high?
- If it is not possible to geographically define a use site, can we geographically define where the pesticide isn't (or wont' be) applied that would provide spatial refinement (*i.e.*, it will not be applied to open water, or urban areas, *etc.*).
- O The range data currently available for listed species are geospatially represented using polygons and they are used in the BEs with the assumption that the species use all areas of their polygon equally throughout the year.
 - CHARGE QUESTION 4a: Are there methods available that would allow for a refined understanding of the distribution of individuals within the range polygons?
 - Are there methods that can be used to help identify areas of concern within a species' range to better estimate the likelihood of exposure – preferred habitat, distribution of individuals (do they cluster, are they territorial, min patches requirements for a home range, fragmentation indices)?
 - Is there biological information that could be used to help identify areas of the range where exposure is unlikely (e.g., due to elevation restrictions) or very likely (e.g., preferred habitat)?
 - How can the effects on timing be better captured (considering both direct and indirect effects)? For example, for direct effects, at the time of year when a pesticide can be applied, is the species there at that time (e.g., is it only there for part of the year because it is migratory?) or at a life-stage when exposure is or is not likely (e.g., is it at an egg stage, subterranean, or in diapause at that time)? What about the resources it depends on (indirect effects)?
 - Should less refined species ranges (e.g., county-level) be treated differently than those that are more refined [keeping in mind that in many cases a species range is not at a sub-county level for various reasons (e.g., no survey data on private lands, wide-ranging species)]? Is the precision of the analysis equal?
 - Can we incorporate this information to apply a weighting to the overlap analysis (see charge question 5a below)?
- O In the pilot BEs, any overlap of the action area with a species range or critical habitat is considered a 'May Affect'.

- CHARGE QUESTION 5a: Does the overlap approach used in the pilot BEs to determine a 'May Affect/No Effect' determination provide an adequate screening process (one that is protective but not unrealistically conservative)?
 - When conducting a GIS overlap analysis using datasets with different levels of resolution, what are methods that could be used to ensure that decisions are made based on the datasets' limits of precision (e.g., how can we best avoid 'false positives' and 'false negatives' in the overlap analyses when considering the limits of precision of the datasets used)?
 - Would using a weighting approach for the likelihood of an overlap be useful when making the Step 1 determinations (instead of using only an overlap of the species range/critical habitat and the action area)? For example, for agriculture uses could we incorporate the number of years a cell was classified as the crop in a weighting approach (while still accounting for the duration of the action)?
 - Are there approaches that could be used to screen out species from further analyses besides solely an overlap of the species range/critical habitat and the action area (e.g., if no Step 1 thresholds for plants are exceeded, can plants that are not biologically pollinated be considered 'No Effect', if no other indirect effects are anticipated)?
- Breakout Group: REFINEMENTS 2 (Refinements to Steps 1 and 2: Non-spatial analysis):
 - O There are a multitude of use patterns on currently registered labels, some which result in potentially higher exposures to non-target organisms than others. For example, although somewhat dependent on chemical fate properties, pesticides applied to large agricultural fields by air are expected to result in higher offsite exposure than pesticides applied to a small area via a ready-to-use spray can.
 - CHARGE QUESTION 1b: Is there a way to identify use patterns that would result in minimal exposures, such as spot treatments, that may not always need to be fully re-assessed for each pesticide going through the consultation process (i.e., by applying what we have learned from an analysis with another pesticide with a similar use pattern)?
 - What type of things regarding the pesticide and use site would need to be considered [e.g., the fate properties of the pesticide, the amount of pesticide applied (e.g., per the label and/or based on usage information), the application method used, potential application sites (e.g., ready-to-use spray can)]?
 - Of these fate properties, how could they be considered keeping in mind use site parameters?
 - Of these use site parameters, how could they be considered (*e.g.*, personal ready-to-use spray can for mosquitos)?

- O There are a subset of listed species that are found in places or environments not expected to result in appreciable exposure to most pesticides (those that are not persistent and do not bioaccumulate) (e.g., species that live wholly or primarily in the open ocean, species only found on non-inhabited islands, and species found only in the arctic regions of Alaska).
 - CHARGE QUESTION 2b: Is there a way to identify species that may not always need to be fully re-assessed for each pesticide going through the consultation process (i.e., by applying what we have learned from an analysis with another pesticides)?
 - Once a species characteristics (e.g., habitat) has been considered, what type of things regarding the fate properties of the pesticide would need to be considered (e.g., aquatic half-life, mobility, bioaccumulation potential, etc.)?
 - Of these fate properties, how could they be considered (e.g., a full assessment might not be needed for pesticides that have a log K_{ow} <4)?
 - What types of biological/ecological attributes of the species would need to be considered (*e.g.*, its habitat)?
 - Of these species characteristics, how can they be considered (this may be different for species and designated critical habitats) (e.g., a full assessment might not be needed for species that live wholly or primarily in the open ocean, species only found on non-inhabited islands, and species found only in the arctic regions of Alaska, not present during windows of application; this may not apply to designated)?
- O The pilot BE process relies on thresholds for mortality that are based on probabilistic effects endpoints (e.g., 1-in-a-million chance of mortality based on the HC₀₅ of a SSD or the lowest LC₅₀/LD₅₀ values) compared to deterministic estimated environmental concentrations (EECs) (e.g., 1-in-15 year peak EEC value). Additionally, sublethal thresholds are assessed using deterministic sublethal thresholds (e.g., NOAECs or LOAECs) and deterministic estimated environmental concentrations (EECs) (e.g., 1-in-15 year peak EEC value). The current approach in the BEs is comparing an exposure value to a threshold for possible exceedances [similar to a risk quotient approach (i.e., exposure/effect)].
 - <u>CHARGE QUESTION 3b</u>: Is there a way to utilize the thresholds that is more informative (for example, in the weight of evidence) and goes beyond a deterministic approach (moving towards a more probabilistic approach for assessing risks as recommended by NAS)?
 - How could joint probability distributions of effects (the thresholds) and exposures (the EECs) be used to help inform the potential for risk?
 - Are there other probabilistic approaches that can help better inform risk at the individual and field levels?

- When making a "May Affect/No effect' determination, what are some practicable methods to better determine where both direct and indirect effects are either 'no effect' or 'discountable' (extremely unlikely to occur)?
 - O For example, could an action be "discountable" for certain species (*e.g.*, when there is no direct exposure or effects expected and no or insignificant/discountable effects to prey, pollinators, *etc.*).
- CHARGE QUESTION 4b: Is there an efficient way to incorporate exposure durations into the analysis of potential effects?
 - The pilot BEs currently compare all effects thresholds to peak EEC values. How can other durations of potential exposure be utilized and related to available toxicity studies (which are conducted under a range of exposure durations)?
 - Are there factors, other than duration, that should be considered when comparing the effects data to the EECs?

WORKSHOP AGENDA (FINAL)

Joint Interim Approaches to NAS Recommendations for Assessing Risks to Endangered and Threatened Species from Pesticides

WEDNESDAY MORNING, JUNE 29 – Plenary Sessions

TIME	SESSION SCHEDULE
8:00	Registration Opens
9:00	Opening Comments
9:15	Overview of Aquatic Breakout Discussion – Chuck Peck (EPA)
9:55	Overview of Refinements Discussion – Melissa Panger (EPA)
10:20	Break
10:40	Overview of Weight of Evidence Discussion – Kris Garber / Elizabeth Donovan (EPA)
11:20	NatureServe on Range Modeling – Regan Smyth, NatureServe
11:45	Breakout Group Instructions – Bernalyn McGaughey (CSI, Workshop Steering Committee)
12:00	Lunch (on own)

WEDNESDAY AFTERNOON, JUNE 29 – Breakout Sessions

TIME	SESSION SCHEDULE					
	AQUATIC 1 (Chuck Peck and George	AQUATIC 2 (Mark Corbin and Al	REFINEMENTS 1 (Bill Eckel/Steve	REFINEMENTS 2 (Melissa Panger	WOE 1 (ANIMALS) (Kris Garber and	WOE 2 (PLANTS) (Elizabeth
	Noguchi)	Barefoot)	Lennartz and Jake Li)	and Karen Myers)	Spencer Mortenson)	Donavon and Bernalyn
GROUPS	Improving Aquatic Modeling: Changes to conceptual and mathematical approaches incorporated into Bins 3 and 4 (flowing waters) • Modifications to EPA's current modeling approach and parameterization to flowing bins • Use of other watershed models (e.g., SWAT, WARP)	Improving Aquatic Modeling: Evaluating watershed model results Use of multiple lines- of-evidence to evaluate watershed model results Role of and metadata requirements for use of monitoring data in evaluating watershed results	Refinements to Steps 1 and 2: Spatial analysis • Methods to better identify pesticide use sites (ag and non-ag) • Methods to better understand the distribution of individuals within a listed species range • Improvements to the overlap analyses between species range and potential pesticide use	Refinements to Steps 1 and 2: Non-spatial analysis Identification of use patterns (e.g., those resulting in minimal exposures) and/or listed species (e.g., those found on uninhabited islands) that may not need to be fully evaluated Methods to utilize thresholds that are more probabilistic Methods to incorporate exposure durations into the analysis of potential effects	Weight of Evidence for Listed Animals Improvements to the evaluation of information and criteria used to draw risk conclusions Incorporation of additional information into the weight of evidence approach	McGaughey) Weight of Evidence for Listed Plants Improvements to the evaluation of information and criteria used to draw risk conclusions Incorporation of additional information into the weight of evidence approach

ROOMS	Leopold (10-12) (12 registered)	Beatie (17-20) (16 registered)	Roosevelt (24) (19 registered)	Stickel (30+) (21 registered)	Hamilton A (16) (16 registered)	Hamilton B (16) (13 registered)
1:00	Aquatic 1 – Charge Questions Set 1	Aquatic 2 – Charge Questions Set 1	Refinements 1 – Charge Questions Set 1	Refinements 2 – Charge Questions Set 1	WOE 1 (Animals) – Charge Questions Set 1	WOE 1 (Plants) – Charge Questions Set 1
3:00	BREAK					
3:30	Aquatic 1 – Charge Questions Set 1	Aquatic 2 – Charge Questions Set 1	Refinements 1 – Charge Questions Set 1	Refinements 2 – Charge Questions Set 1	WOE 1 (Animals) – Charge Questions Set 1	WOE 1 (Plants) – Charge Questions Set 1
5:30	ADJOURN					
5:45	NO-HOST SOCIAL - Buffalo Wild Wings (Next Door to Meeting Area)					

THURSDAY, JUNE 30 – Breakout Sessions

TIME	SESSION SCHEDULE						
8:30	Registration Opens						
GROUPS	AQUATIC 1	AQUATIC 2	REFINEMENTS 1	REFINEMENTS 2	WOE 1 (ANIMALS)	WOE 2 (PLANTS)	
9:00	Aquatic 1 – Charge Questions Set 2	Aquatic 2 – Charge Questions Set 2	Refinements 1 – Charge Questions Set 2	Refinements 2 – Charge Questions Set 2	WOE 1 (Animals) – Charge Questions Set 2	WOE 1 (Plants) – Charge Questions Set 2	
10:30	BREAK						
11:00	Aquatic 1 – Charge Questions Set 2	Aquatic 2 – Charge Questions Set 2	Refinements 1 – Charge Questions Set 2	Refinements 2 – Charge Questions Set 2	WOE 1 (Animals) – Charge Questions Set 2	WOE 1 (Plants) – Charge Questions Set 2	
12:30	LUNCH (on own)						
1:30	Aquatic 1 – Finalize Responses	Aquatic 2 – Finalize Responses	Refinements 1 – Finalize Responses	Refinements 2 – Finalize Responses	WOE 1 (Animals) – Finalize Responses	WOE 1 (Plants) – Finalize Responses	
2:30	BREAK						
2:45	Final Overview – Breakout Groups Report Out (30 min each)						
5:45	Wrap-up						
6:00	Adjourn						

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The behaviour of 39 pesticides in surface waters as a function of scale

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Abstract:

A portion of applied pesticides runs off agricultural fields and is transported through surface waters. In this study, the behaviour of 39 pesticides is examined as a function of scale across 14 orders of magnitude from the field to the ocean. Data on pesticide loads in streams from two US Geological Survey programs were combined with literature data from field and watershed studies. The annual load as percent of use (LAPU) was quantified for each of the fields and watersheds and was used as the normalization factor across watersheds and compounds. The in-stream losses of each pesticide were estimated for a model stream with a 15 day travel time (similar in characteristics to the upper Mississippi River). These estimated in-stream losses agreed well with the observed changes in apparent LAPU values as a function of watershed area. In general, herbicides applied to the soil surface had the greatest LAPU values and minimal in-stream losses. Soil-incorporated herbicides had smaller LAPU values and substantial in-stream losses. Insecticides generally had LAPU values similar to the incorporated herbicides, but had more variation in their in-stream losses. On the basis of the LAPU values of the 39 pesticides as a function of watershed area, a generalized conceptual model of the movement of pesticides from the field to the ocean is suggested. The importance of considering both field runoff and in-stream losses is discussed in relation to interpreting monitoring data and making regulatory decisions.

KEY WORDS pesticides; insecticides; herbicides; runoff; stream; load; modelling; surface water

INTRODUCTION

The movement of pesticides from agricultural fields and through the surface water network has been studied extensively. Although each pesticide behaves differently, the processes that govern their behaviour and fate have been identified and, to some extent, quantified. Atrazine was used as an example of a pesticide that exhibits ideal behaviour in its movement from agricultural fields to the ocean (Capel and Larson, 2000). From a field runoff perspective, atrazine is ideal because it is widely used, typically applied on the bare soil surface, and is observed in most runoff events. From a surface water perspective, it is one of the most commonly observed herbicides in streams and rivers, and has relatively slow loss processes from the water column. By using the parameter of annual load (in field runoff or in the stream) normalized to annual use (load as percent of use, LAPU), the behaviour of atrazine in 414 watersheds across the range of scales was easily compared. It was observed that the LAPU value of atrazine did not vary substantially with scale in watersheds that ranged through 14 orders of magnitude in area. The variability that did exist in the LAPU values was attributed to year-to-year differences in weather within a given watershed and differences in the terrestrial characteristics among the various watersheds. When the logarithm of annual atrazine load was regressed against the logarithm of annual atrazine use, the slope was very close to unity (1.04 ± 0.02) , suggesting that the average runoff behaviour is consistent across a wide range of watershed areas and characteristics. The central tendency of the atrazine LAPU value was defined as the median smallscale LAPU (small scale means agricultural fields and watersheds < 100 000 ha). (Only the small watersheds

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were used to minimize the effect of any in-stream loss of atrazine. Although the losses will be minimal for atrazine, when this method is applied to other pesticides discussed in this paper the losses could be substantial.) The atrazine median small-scale LAPU was 0.66%. On the basis of these observations, Capel and Larson (2000) concluded that the extent of atrazine runoff was determined by the characteristics of atrazine itself (physical/chemical properties, formulation, and application method), as well as terrestrial or climatic factors. This paper will examine 39 pesticides in a similar fashion to determine whether a similar phenomenon is observed.

Many different organic compounds are used to control pests in agricultural crops. Wauchope (1978, p. 450), in his review of the literature on pesticide runoff from agricultural fields, wrote, 'pesticides are different. The only property that these chemicals have in common is their broad function as tools for crop protection. Once they leave the spray nozzle they show vastly different persistences, mobilities, and toxicities'. Each individual organic pesticide has its particular set of physical/chemical properties (solubility, vapour pressure, Henry's law constant, etc.). Each pesticide is generally marketed in only one or a few different formulations (granular, wettable powder, emulsifiable concentrate, etc.) and applied in the field by one or more different methods (surface, soil incorporated, foliar, etc.). These three attributes of a particular pesticide are often interrelated. As an example, butylate, a herbicide used on corn, has a relatively high vapour pressure (Table I) and, consequently, is almost always incorporated into the soil (applied at depth) so that its efficacy will not be lost due to volatilization to the atmosphere.'

Concentrations of 39 current-use pesticides (Table I) have been measured in rivers across the United States in two US Geological Survey (USGS) Programs [National Stream-Quality Accounting Network (NASQAN) and National Water-Quality Assessment Program (NAWQA)]. These data have been used to calculate annual LAPU values. The LAPU values from the USGS programs were combined with LAPU values for studies of the 39 pesticides in runoff and in streams, which are reported in the scientific literature. The LAPUs for individual pesticides from field-scale and watershed-scale studies are examined to help understand the controls on the extent of field runoff and in-stream losses. By comparing the LAPUs for the different chemicals, the relative importance of chemical properties, formulations, and application practices are discussed. On the basis of these observations, a generalized conceptual model of the movement of pesticides from the field to the ocean is suggested.

Factors controlling field runoff

The extent to which a pesticide runs off an agricultural field is determined by the unique combination of climatic, terrestrial, chemical, and management factors that characterize each field, crop, and year combination. Each of these factors has been studied in detail, and numerous reviews on this subject have been published (Wauchope, 1978; Weber *et al.*, 1980; Wauchope and Leonard, 1980; Leonard, 1988, 1990; Willis and McDowell, 1982).

The most important factor controlling the extent of runoff is rainfall, especially the timing and intensity of the first substantial rain after application. The greatest amounts of pesticides are lost from the field when the first runoff-producing rain occurs soon after application. Subsequent runoff-producing rains tend to cause lesser amounts of pesticides to leave the field. Many field runoff studies have used simulated rain to control the timing and amount of the precipitation (Capel *et al.*, 2001). Frequently, investigators exceed normal rainfall amounts in these studies to simulate worse-case conditions. Wauchope (1978) refers to these as catastrophic rain events, and LAPUs >2% are often observed.

Terrestrial factors also influence the extent of pesticide runoff. Important factors that have been identified include soil-particle size and organic-matter content, and topographic slope. Particle size can influence the rate of infiltration of water; generally, smaller particle sizes yield lower infiltration rates and more runoff. Particle size and soil organic-matter content influences runoff by affecting the extent of sorption of the pesticide. Chemicals strongly sorbed to soil particles tend to leave the field associated with particles, whereas chemicals weakly sorbed tend to leave the field in the aqueous phase. Efforts to control soil

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Table I. Agricultural pesticide use, properties, and estimated in-stream loss

Pesticide (use ^a)	Major application method ^b	National use rank ^c	Soil half-life (days) ^d	Aqueous half-life group ^e	$\log K_{ m H}{}^{ m f}$	$\log K_{\rm oc}{}^{\rm g}$	Major loss process ^h	Estimated % lost in 15 days ⁱ
Alachlor (H)	sur	7	27	Е	-7.67	2.23	T	14
Atrazine (H)	sur	1	173	G	-8.55	2.00	T	2
Azinphos-methyl (I)	fol	48	10	C	-8.51	2.61	T	77
Benfluralin (H)	inc	105	80	C	-3.54	3.95	T,V	95
Butylate (H)	inc	19	28	E	-4.09	2.60	V	74
Carbaryl (I)	fol	32	14	C	-9.36	2.36	T	77
Carbofuran (I)	inc	24	41	C	-9.31	2.02	T	77
Chlorpyrifos (I)	inc	12	43	C	-4.97	3.78	T	86
Cyanazine (H)	sur	3	13	E	-11.53	2.30	T	14
DCPA (H)	sur	76	50	F	-5.57	1.18	T	45
Diazinon (I)	fol	62	7	E	-6.40	2.76	T	16
Disulfoton (I)	fol	60	37	D	-5.67	3.25	T	45
EPTC (H)	inc	13	18	C	-5.00	2.30	T	85
Ethalfluralin (H)	inc	47	41	В	-3.90	3.71	T	100
Ethoprop (I)	inc	67	29	E	-6.85	2.15	T	14
Fonofos (I)	fol	45	37	D	-5.17	2.94	T,V	54
Lindane (I)	sur	161	423	G	-5.84	3.00	V	10
Linuron (H)	sur	54	82	D	-6.13	2.91	T	40
Malathion (I)	fol	40	9	В	-7.65	3.26	T	99
Methyl parathion (I)	fol	16	10	D	-6.69	3.70	T	42
Metolachlor (H)	sur	2	141	E	-7.64	2.26	T	14
Metribuzin (H)	sur	46	47	F	-10.46	1.71	T	36
Molinate (H)	pat	25	13	C	-5.85	1.92	T	79
Napropamide (H)	inc	99	48	C	-9.09	2.66	T	77
Parathion (I)	fol	55	14	D	-6.63	3.88	T	44
Pebulate (H)	inc	90	8	D	-4.59	2.62	T,V	70
Pendimethalin (H)	sur	9	174	F	-4.92	4.13	T,V	67
Permethrin (I)	fol		42	D	-5.73	4.59	T,S	66
Phorate (I)	sur	34	37	F	-5.01	2.82	T,V	58
Pronamide (H)	sur	127	45	F	-5.74	2.90	T	43
Propachlor (H)	sur	31	9	D	-6.97	1.90	T	37
Propanil (H)	sur	20	1	A	-7.27	2.17	T	100
Propargite (I)	fol	39	84	F	-7.47	4.61	S,T	65
Simazine (H)	sur	26	89	D	-8.47	2.11	T	36
Terbacil (H)	sur	93	212	G	-9.83	1.74	T	2
Terbufos (I)	inc	21	12	В	-4.62	2.70	T	99
Thiobencarb (H)	pat	64	19	C	-3.54	2.95	T,V	95
Triallate (H)	inc	53	74	E	-4.95	3.38	V	47
Trifluralin (H)	inc	10	81	E	-4.01	4.14	V	79

^a H: herbicide, I: insecticide.

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b Sur: soil surface applied; inc: incorporated into soil; fol: foliar applied; pad: added to rice paddy (Wauchope *et al.*, 1992).

^c Agricultural use rank by mass applied (Gianessi and Anderson, 1996).

d USDA, (1999).

e A: ~0.5-1 day; B: ~1-4 days; C: ~4-12 days; D: ~12-40 days; E: ~40-120 days; F: ~120-420 days; G: ~420-1200 days; Mackay

et al. (1997). f log Henry's law constant ($K_{\rm H}$, 20 °C, atm m³ mol⁻¹; USDA, 1999). g log organic-carbon normalized water–solid distribution coefficient ($K_{\rm oc}$, 1 kg⁻¹; USDA, 1999). h S: sorption/sedimentation; T: transformation; V: volatilization. Two major processes are identified, if they differ by less than a factor of two.

i Estimated losses are for the conditions: POC = 1 mg l^{-1} ; mean depth, 2 m; mean water velocity, 1 m s^{-1} ; temperature, 20 °C; wind speed, 1 m s^{-1} .

erosion could significantly reduce the runoff of strongly sorbed pesticides, but would have little effect on others.

The chemical structure of a pesticide determines its properties. These include water solubility, acid dissociation constant, ionic charge, vapour pressure, and resistance to physically, chemically, and biologically induced transformation reactions. For nonionic compounds, the water solubility is inversely related to the extent of sorption to soil particles. Pesticides with relatively high vapour pressures are easily lost from the soil via volatilization if they are not incorporated into the soil during application. Loss to the atmosphere influences the extent of runoff by diminishing the amount of the pesticide available in the soil. The same holds true for the kinetics of the transformation reactions. The faster any type of reaction transforms the pesticide in the field, the less is available over the season to be lost in runoff.

Wauchope (1978) showed that one way of organizing the runoff behaviour of various pesticides is by their formulations. Pesticides formulated as wettable powders (generally herbicides applied to the soil surface) had the greatest tendency toward runoff of the pesticides still used in agriculture. (The organochlorine insecticides had the greatest tendency to runoff, but most of them are no longer in use.) Wauchope (1978) suggested that a LAPU of about 2% would be a good estimate for compounds formulated as wettable powders for fields with low slopes. Wauchope (1978) also suggested that pesticides formulated as an emulsion had LAPUs of 1% or less. Many of the low solubility compounds and foliar-applied insecticides are in this group. The pesticides that generally had the lowest LAPUs (<0.5%) included the soil-incorporated compounds and the highly water-soluble pesticides that were formulated as aqueous solutions. If only organic pesticides are considered, paraquat was the only consistent exception to these general observations. Although paraquat is highly water soluble, it is cationic and, therefore, strongly associates with soil particles.

Many types of agricultural practice come into play when determining the extent of runoff of pesticides, as well as water and soil, including choice of crop, chemical application method, chemical formulation, tillage method, and best management practices (BMPs). The choices made are based on a consideration of practical, economic, and environmental concerns. The choice of crop and chemical is dependent on climate and soil. The choice of chemical, application method, and tillage method is dependent on the equipment available to the farmer and the application method recommended by the chemical manufacturer. The choice of BMP, such as buffer strips, contour ploughing, or reduced tillage, generally is based on local environmental concerns. Many BMPs are designed to decrease the amount of soil that is lost to surface waters, but a few are designed to reduce water runoff. The different BMPs affect the runoff of the more water-soluble pesticides to various extents.

After a pesticide runs off the field and enters a stream, its behaviour and fate will be governed by the properties of the chemical (particularly water solubility, Henry's law constant, and persistence) and the properties of the stream (particularly travel time, depth, solids concentration, and the physical, chemical, and(or) microbiological constituents that cause transformation). Although the behaviour of each chemical in each river will be unique, there are ranges of chemical and environmental properties that bracket most situations. By examining these ranges, the relative importance of the three general loss processes (transformation, volatilization, and sorption/sedimentation) can be evaluated for individual pesticides in a variety of riverine environments. These model equations, given below, are illustrated with a simple example. The model equations then will be applied to the 39 pesticides included in this study to help understand the field observations.

METHODS

Sampling and analysis

Samples were obtained from the largest rivers (Colorado, Columbia, Mississippi, and Rio Grande Rivers and their major tributaries) in the USA from October 1996 through September 1998 as part of the NASQAN program. For a given pesticide, only those watersheds that met minimum use criteria (1 kg km⁻²) are included

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in this analysis. The number of NASQAN watersheds varies from 0 to 14, depending on the compound. A more detailed description of the watersheds, details of the sampling schedule and the sampling techniques, are described by Hooper *et al.* (2001) and Kelly and Hooper (2001).

Samples were also obtained from 43 streams and rivers from October 1992 through September 1994 as part of the NAWQA program. For a given pesticide, only those watersheds that met minimum use criteria (1 kg km⁻²) are included in this analysis. The number of NAWQA watersheds varies from 0 to 34, depending on the compound. The smaller watersheds generally were intensively cropped and indicative of the agriculture of the region. A more detailed description of the watersheds, the details of the sampling schedule and the sampling techniques are described by Larson *et al.* (1999) and Shelton (1994).

The NASQAN and NAWQA programs used the same analytical procedure for the pesticides. Briefly, a 11 water sample was processed through a combusted 142 mm glass-fibre filter (nominal $0.7 \mu m$ pore openings). The filtered water was spiked with surrogates. After the pesticides were isolated from the water with a 500 mg octadecyl solid-phase extraction column, the column was dried and the pesticides eluted with solvent. The solvent volume was reduced with a gentle stream of nitrogen. The extract then was analysed by gas chromatography/mass spectrometry using selective ion monitoring. The method detection limits ranged from 1 to 10 ng 1^{-1} . Details of the analytical procedure, including quality assurance results, are in Zaugg et al. (1995).

Literature data of LAPU values from studies for fields and streams

The international scientific literature was searched for studies that quantified the selected pesticides in field runoff or streams by means of two computerized bibliographic databases: Chemical Abstracts and AGRICOLA. Only articles that contained enough information to calculate a LAPU value were retained. The areas of the controlled field studies ranged from 0.000 023 to 60 ha. The areas of the watershed studies ranged from 58 to 315 620 000 ha. Throughout this paper, both of these groups are referred to as watersheds.

All controlled plot and field studies that were conducted outside of the laboratory and lasted for more than 1 day were included in this analysis without screening. The duration of most field studies was weeks to months. A few, with a shorter duration, employed simulated rain. Because the majority of pesticide runoff almost always occurs in the first major runoff event following application, the results of the short duration studies are similar to the results of the studies of longer duration. The *a priori* decision to include all studies with duration greater than 1 day was made to limit any bias introduced by deleting certain field studies. The exception to this is the single field-scale study that examined EPTC (Spencer and Cliath, 1991). This study examined the loss of EPTC after it was put into irrigation water for alfalfa. Because most EPTC is used on corn and applied as incorporated herbicide, the losses in the irrigation water study would not be representative of the major use of this compound and, therefore, were not included in Table II.

Load calculations and pesticide use estimates

The annual loads of the pesticides in streams from both the NASQAN and NAWQA programs were calculated as described in Larson *et al.* (1995) by summing up estimated daily loads. The daily loads were calculated by multiplying the daily stream discharge by the daily concentration. Daily discharge values were available, but pesticide concentrations were measured less frequently. Pesticide concentrations for days that were not sampled were estimated by linear interpolation from the concentrations measured on the closest preceding and following days in which pesticides were quantified. If the pesticide was not detected, a value of zero was used for the concentration. The loads of the pesticides from studies published in the literature were used as reported. In some cases, loads that were reported as '<' were removed from the statistical analysis described below when the data were transformed by the base-10 logarithm.

For the data from the NASQAN and NAWQA programs, pesticide use was based on county-level use estimates (Gianessi and Anderson, 1996). The estimated use of each pesticide in each county in the watershed was summed to yield a total use value. For counties only partially in the watershed, the pesticide's use was

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Table II. Summary of field-based and watershed-based LAPU values of the 39 pesticides. The median small-scale LAPU is based on observations from both

Compound	Ľ	ield-ba	ased observ	Field-based observations (<60 ha)	Median small-scale	•		Stre	Stream-based observations (>100 ha)	ations (>100	ha)	
	8	% a	% <a median<="" th=""><th>Mean ± SD</th><th>- LAPU (%)</th><th>A</th><th>All</th><th>Watersl</th><th>Watersheds < 100 000 ha</th><th></th><th>Watersheds > 10 000 000 ha</th><th>ha</th>	Mean ± SD	- LAPU (%)	A	All	Watersl	Watersheds < 100 000 ha		Watersheds > 10 000 000 ha	ha
						×	% < a	% <a median<="" th=""><th>Mean \pm SD</th><th>N Median</th><th>$Mean \pm SD$</th><th>\geq</th>	Mean \pm SD	N Median	$Mean \pm SD$	\geq
Alachlor	113	9	0.36	2.1 ± 0.3	0.27	146	5	0.12	0.38 ± 0.83	34 0.13	0.17 ± 0.15	34
Atrazine	181	9	92.0	1.7 ± 0.9	99.0	226	\mathcal{E}	0.47	1.7 ± 3.0	95 1.5	1.9 ± 1.5	51
Cyanazine	69	7	0.10	3.7 ± 0.4	89.0	135	S	0.13	1.1 ± 2.5	28 0.82	1.2 ± 1.1	43
DCPA	\mathcal{E}	0	1.4	1.3 ± 0.096	1.2	5	0	1.2	1.2 ± 1.1	3 –	1	0
Linuron	16	9	0.040	0.45 ± 0.88	0.038	19	28	0.024	0.090 ± 0.15	10 <	٧	9
Metolachlor	102	\mathcal{E}	09.0	1.2 ± 0.9	0.50	175	3	0.25	1.0 ± 1.6	54 0.80	1.0 ± 0.82	5
Metribuzin	95	_	0.71	1.8 ± 0.5	0.70	61	∞	0.053	0.40 ± 0.73	5 0.28	0.25 ± 0.14	9
Pendimethalin	9	17	0.046	0.035 ± 0.024	0.0050	71	4	0.0043	0.013 ± 0.018	30 <	0.0066 ± 0.0092	2
Pronamide	0		I	1	ا م	1	0	0.020	0.020	1		0
Propachlor	11	0	0.25	1.4 ± 0.9	0.22	15	27	0.051	0.065 ± 0.053	4 0.0073	0.040 ± 0.068	9
Propanil	0	1	I	1	ا ٩	1	0	6.4	1	- 0		0
Simazine	26	23	0.16	0.82 ± 0.4	0.52	40	3	1.6	2.6 ± 2.9	12 5.2	6.5 ± 4.7	4
Terbacil	0		1	1	ا ۽	1	0	0.73	0.73	1	1	0
Benfluralin	0			l	٧	4	100	٧	٧	4	1	0
Butylate	0			I	0.0039	38	4	0.0039	0.082 ± 0.21	13 <	0.019 ± 0.059	15
$EPTC^{1}$	0		1	1	0.034	82	12	0.034	0.16 ± 0.47	21 0.0080	0.021 ± 0.037	37
Ethalfluralin	0			l	٧	12	29	٧	0.13 ± 0.42	10	1	0
Napropamide	0			1	1.6	3	0	1.6	1.6 ± 0.85	2 —		0
Pebulate	0			1	0.00027	S	40	0.0003	1.0 ± 1.7	3		0
Triallate	0				0.0023	10	20	0.0022	0.012 ± 0.020	٧	٧	0
Trifluralin	36	Ξ	0.18	0.23 ± 0.25	0.054	69	26	0.012	0.06 ± 0.15	25 0.0043	0.0064 ± 0.0087	2,
Molinate	0			1	4.9	3.)	4.9	4.9 ± 6.7		1	

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0 0 0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	
0 — 6 < < 14 < < 15 0.090 30 0.0032 5 0.045 5 < < 5 < < 16 0.020 0 — 3 < < 6 < < 6 < < 6 < < 6 < 6 < 6 < 7	
0 27 27 27 27 27 27 119 119 110 110 110 110 20 22 24 24 240 350 350 360 37 37 38 38 38 38 38 38 38 38 38 38 38 38 38	
$\begin{array}{c} - \\ 0.32 \\ 0.033 \\ 0.32 \\ 0.032 \\ 0.0085 \\ 0.0080 \\ 0.00045 \\ 0.0045 \\ 0.0045 \\ 0.0009 \\ 0.0090 \\ 0.019 \\ < < \\ < \\ 0.00080 \\ 0.0106 \ (N = 10) \\ 0.016 \ (N = 6) \\ 0.016 \ (N = 14) \\ 0.078 \ (N = $	
$\begin{array}{c} -\\ 0.59 \pm 0.59 \\ 0.14 \\ 2.3 \pm 0.2 \\ 0.15 \pm 0.20 \\ 0.052 \pm 0.037 \\ -\\ -\\ -\\ -\\ -\\ -\\ -\\ -\\ 0.00045 \pm 0.00021 \\ -\\ -\\ 0.00045 \pm 0.00021 \\ -\\ -\\ 0.14 \pm 0.13 \\ 0.28 \pm 0.20 \\ 0.038 \pm 0.058 \\ -\\ -\\ -\\ -\\ -\\ -\\ -\\ -\\ -\\ -\\ -\\ -\\ -$	
0	
Thiobencarb Azinphos-methyl Carbaryl Carbaryl Carbofuran Chlorpyrifos Disulfoton Ethoprop Fonofos Lindane Malathion Methyl parathion Permethrin Phorate Propargite Terbufos Surface herb ^c	

^a Percent less of watersheds in which a LAPU value could not calculated due to water concentrations that were below the detection limit.

^b Herbicides with median small-scale LAPUs based only on one small watershed observation: pronamide 0.020%, propanil 6.4%, and terbacil 0.73%.

^c The high and low LAPU values were eliminated and the remaining values averaged.

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prorated on the basis of percentage of land used in row crop agriculture in the watershed (Gilliom and Thelin, 1997). For the studies from the literature, the masses of the pesticides applied were used in this analysis as originally reported.

Factors and model equations of in-stream losses of pesticides

Pesticides can undergo physically, chemically, and (or) biologically induced transformation reactions. Depending on the conditions of the environments, different types of transformation process can act simultaneously on a pesticide, but generally one reaction is the most important. The rate of transformation is often described by pseudo first-order kinetics with a rate constant k_t that is the sum of all physically, chemically, and (or) biologically induced reactions. The percent loss as a function of time t can be calculated by

$$(\ln C/C_{\rm o}) \times 100 = -k_{\rm t}t\tag{1}$$

where C_0 is the initial total concentration and C is the total concentration at time t. Figure 1(a) shows the percent loss of a pesticide as a function of surface water half-life for a range of travel times that bracket most riverine systems. As an example, for a 15 day travel time, typical of the Mississippi River from Iowa to the Gulf of Mexico (Pereira and Rostad, 1990), only those pesticides that have aquatic half-lives less than about 47 days will have losses $\geq 20\%$.

The rate loss of a pesticide from the water column via volatilization is a function of chemical properties (Henry's law constant and diffusivities in air and water), riverine properties (depth, water temperature and turbulence), and atmospheric properties (air temperature and wind speed). Volatilization is often modelled after the two-film theory, which suggests that the mass flux of the contaminant is the product of the overall mass transfer coefficient v_{OL} and the difference between the concentrations of the pesticide in the water and air. Often expressed as the resistance to air—water transfer, $1/v_{OL}$ is the sum of the resistance of transfer through the two stagnant films (water and air)

$$1/\nu_{\rm OL} = 1/\nu_{\rm W} + 1/\nu_{\rm A} \tag{2}$$

where v_W and v_A are the mass transfer coefficients in the stagnant water and air films respectively. Schwarzenbach *et al.* (1993), in their review of the literature, suggest that v_W and v_A can be estimated by the relationships

$$\nu_{\rm W} \approx (D_{\rm w,i}/D_{\rm w,O_2})^{0.57} (4 \times 10^{-5} (u_{10})^2 + 4 \times 10^{-4})$$
 (3)

and

$$\nu_{\rm A} \approx (D_{\rm a,i}/D_{\rm a,H_2O})^{0.67} (0.2u_{10} + 0.3)(K_{\rm H}/RT)$$
 (4)

where $D_{w,i}$ (cm² s⁻¹), is the diffusivity of compound i in water, D_{w,O_2} (cm² s⁻¹) is the diffusivity of oxygen in water, $D_{a,i}$ (cm² s⁻¹) is the diffusivity of compound i in air, D_{a,H_2O} (cm² s⁻¹) is the diffusivity of water in air, u_{10} (m s⁻¹) is the wind speed at 10 m above the river surface, R (0·082 l atm mol⁻¹ K⁻¹) is the gas constant, T(K) is the temperature, and K_H (l atm mol⁻¹) is Henry's law constant.

Because only the dissolved fraction of the pesticide is available for volatilization, the rate of loss of a pesticide to the atmosphere via volatilization R_v , assuming its air concentration is zero, is

$$R_{\rm v} = -k_{\rm v}C(1 - f_{\rm p}) = -(\nu_{\rm OL}/z)C(1 - f_{\rm p}) \tag{5}$$

where k_v is the pseudo first-order rate constant, f_p is the fraction of the pesticide associated with the particulate phase, and z(m) is the mean depth of the river. For a given wind speed, this equation can be rearranged and solved for a specific degree of loss of the pesticide. Assuming a wind speed of 1 m s⁻¹, Figure 1(b) shows the ranges of K_H values and riverine depths that would result in a 20% loss of a pesticide for a range of riverine travel times. Using the example of the Mississippi River described above (z = 2 m), only those pesticides with a K_H value $\geq 1 \times 10^{-3}$ would have a loss of 20% in a 15 day travel time.

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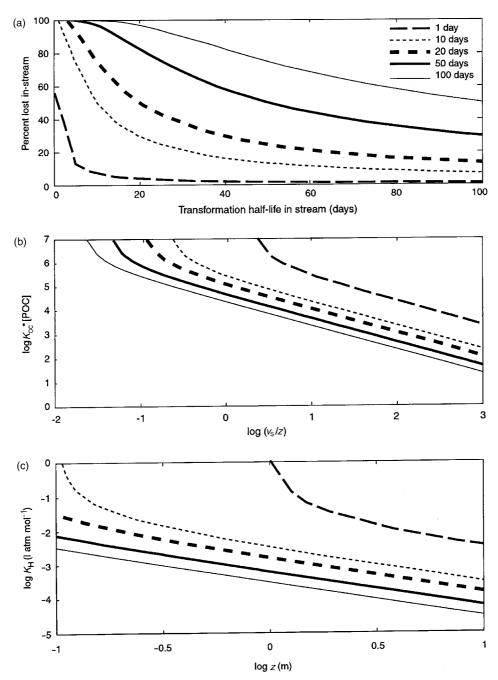


Figure 1. (a) Percent in-stream loss of a pesticide as a function of surface water half-life for a range of travel times that bracket most riverine systems. (b) Typical ranges of Henry's law constant $K_{\rm H}$ and mean stream depth that would result in a 20% loss of a pesticide for a range of travel times. (Average wind speed assumed to be 1 m s⁻¹.) (c) Typical ranges of the product of organic-carbon based sorption coefficient $K_{\rm oc}$ and particulate organic carbon concentration (POC) and the product of mean stream depth and particle settling velocity that would result in a 20% loss of a pesticide for a range of travel times. In all three graphs, the lines represent a 20% loss for a river similar to the upper Mississippi River and a 15 day travel time

The rate loss of a pesticide from the water column via sorption/sedimentation is conceptually a two-step process. The first step, sorption, is largely governed by the chemical. The physics of the river and the types of aquatic particle largely govern the second step, sedimentation. The driving force for sorption of nonionic pesticides is their hydrophobicity, which is quantified through water solubility. Several investigators (see review in Schwarzenbach *et al.* (1993)) have shown that the extent of sorption for a given chemical is a function of its water solubility and the fraction of the aquatic particle that consists of organic carbon f_{oc} . Wanner *et al.* (1989) have used these relations to calculate the fraction of the chemical in the particulate phase f_p

$$f_{p} = (K_{oc}[POC])/(1 + K_{OC}[POC])$$
(6)

where $K_{\rm OC}(1~{\rm kg^{-1}})$ organic carbon), is the organic-carbon normalized distribution coefficient and [POC] (kg 1^{-1}) is the concentration of particulate organic carbon. This can be rearranged to isolate the effect of the chemical ($K_{\rm oc}$) and riverine (POC) properties on the fraction in the particulate phase

$$K_{\rm OC}[POC] = (f_{\rm p} \times 10^{-6})/(1 - f_{\rm p})$$
 (7)

The factor of 10^{-6} is for unit conversion from 1 kg^{-1} for POC in Equation (6), to the units of mg 1^{-1} , the units in which POC is normally reported.

Once the pesticide is sorbed to the particle, it can be removed from the water column through sedimentation. Wanner *et al.* (1989) have suggested that the removal R_s can be described as

$$R_{\rm s} = -k_{\rm s} f_{\rm p} C = -(v_{\rm s}/z) f_{\rm p} C \tag{8}$$

where $k_{\rm s}$ is the pseudo first-order rate constant for sedimentation, $v_{\rm s}$ is the mean settling velocity, and z is the mean depth of the river. Figure 1(c) shows the range of values of chemical and riverine properties that would result in a 20% loss of a pesticide for a range of riverine travel times. In Figure 1(c), the y-axis brackets the product of the normal ranges of $K_{\rm oc}$ (1 to 10 000 1 kg⁻¹) and [POC] (1 to 100 mg l⁻¹) and the x-axis brackets the product of the normal ranges of $v_{\rm s}$ (0·01 to 10 m day⁻¹) and z (0·1 to 10 m). As in the example above ($v_{\rm s}=2$ m day⁻¹, z=2 m, [POC] = 1 mg l⁻¹), only those chemicals with $K_{\rm oc}>6\times10^4$ would have losses of \geq 20% in a 15 day travel time.

RESULTS

Plot- and field-scale observations of LAPU

The statistical summary of the LAPUs for the 39 individual compound is presented in Table II. The scales of these plot and field studies ranged from 0.23 m² to 60 ha (about six orders of magnitude). For 17 of the 39 compounds, no literature studies were found that reported a LAPU or the data needed to calculate a LAPU. For another eight compounds, fewer than ten LAPUs are reported in the literature. In this group, many of the values reported for a compound were from a single study.

The relationship between the mean and median LAPU values differs among individual compounds. The mean was greater than the median for 16 of the 22 compounds, although the difference between the mean and median LAPU values was less than a factor of two for 14 of the 22 compounds. The largest difference between the mean and median was for cyanazine, which had a very high mean LAPU value because one study used simulated rain and reported ten observations with a LAPU >10% (Baker *et al.*, 1978). There were ten compounds with a mean LAPU >1%, a median LAPU ≥0.6%, or both. This group included seven surface-applied herbicides (alachlor, atrazine, cyanazine, DCPA, metolachlor, metribuzin, and propachlor) and three insecticides (carbofuran, fonofos, and terbufos). Because DCPA has only three observations, it is uncertain whether DCPA belongs in this group of pesticides with high LAPU values.

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The surface-applied corn and (or) soybean herbicides (alachlor, atrazine, cyanazine, metolachlor, and metribuzin) were by far the most commonly studied compounds at the plot and field scale (Table II). This group of five compounds accounts for 72% of all of the LAPU values reported for the 39 compounds. Five insecticides had at least ten reported LAPU values, but a LAPU value was reported for only one soil-incorporated herbicide (trifluralin). It should be noted that the three groups have substantially different numbers of observations of LAPU. There were 619, 36, and 119 observations of LAPU for the surface-applied herbicides, soil-incorporated herbicides and insecticides respectively.

All three groups also had some observations of LAPUs that were reported as zero or less than the minimum quantifiable value (Table II). These zero and less-than values represent 5%, 11%, and 10% of the LAPU values for the surface-applied herbicides, soil-incorporated herbicides, and insecticides respectively. The largest observed LAPU values (those >90th percentile) ranged from 5.4 to 23%, 0.47 to 1.1% and 1.9 to 11% for the surface-applied herbicides, soil-incorporated herbicides and insecticides respectively. A t-test done on the LAPU data after transformation using the cubic root obtained a nearly normal distribution. The mean of the LAPUs for the surface-applied group was significantly different from the means of the soil-incorporated and insecticide groups (p < 0.001 for both).

In his review of pesticides in runoff, Wauchope (1978) made some generalizations based on pesticide formulation and application method. Although some of the studies included in this analysis were also used in Wauchope's work, a considerable amount of additional research was conducted on the runoff characteristics of these chemicals. He suggested that the LAPUs of surface-applied herbicides (triazines and other wettable powders), soil-incorporated herbicides, and insecticides would be about 2%, 0.5%, and 0.5% respectively. This generalization, made over 20 years ago, is in good agreement with the mean LAPU values of the three groups (1.8%, 0.23%, and 0.84% for the surface-applied herbicides, soil-incorporated herbicides and insecticides respectively).

Estimated in-stream losses of specific pesticides

As pesticides run off the field and into the surface water system, they enter an environment that is water dominated rather than particle dominated. The extent of in-stream losses of individual pesticides will vary because of the characteristics of the streams through which they are transported, as well as the characteristics of the chemical itself. The surface water system spans a continuum of streams from agricultural ditches draining a few farm fields up to the large regional rivers that drain into the ocean. Given this diversity, the characteristics of the streams (physical, chemical, and biological) will vary tremendously. It is not possible, in the context of this paper, to model specifically how individual riverine environments will process individual pesticides. Therefore, a 'standard' stream is defined to compare the relative losses of the different pesticides. This stream is defined by the input parameters described above: mean depth, 2 m; mean water velocity, 2 m day⁻¹; mean wind speed, 1 m s⁻¹; temperature (air and water), 20 °C; POC, 1 mg/l⁻¹; neutral pH; a 'typical' microbiological community; and 'typical' spring sunlight conditions. This 'standard' stream is representative of the upper Mississippi River in early June, when the largest load of pesticides is transported.

Because each of the in-stream loss processes is acting on the pesticide simultaneously, the rate constants must be summed to yield an overall rate of loss. On the basis of Equations (1), (5), and (8), the one or two most important loss processes for each chemical for these stream conditions are presented in Table I.

The pesticides in this study were chosen with the criterion that they exist predominately in the dissolved phase in aqueous environments, because only the filtered water was analysed. Because of this, only two pesticides, propargite and permethrin, have sorption/sedimentation as one of their important loss processes. There are some hydrophobic pesticides (i.e. DDT, chlordane) not targeted in this study that would readily be lost from the water column through sorption/sedimentation.

Volatilization is one of their dominant loss processes for ten of the 39 pesticides. Five of these pesticides (benfluralin, pebulate, pendimethalin, triallate, and trifluralin) are herbicides that are generally incorporated in the soil during application because of their volatility. It is interesting to note that other soil-incorporated

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herbicides (EPTC, ethalfluralin, and napropamide) were calculated to be lost faster through transformation reactions than through volatilization. Three of the insecticides (fonofos, lindane, and phorate) were calculated to be lost predominately through volatilization. Finally, thiobencarb, a herbicide normally applied to standing water in rice paddies, can be lost through volatilization as well as transformation.

In-stream transformation (chemically and (or) biologically induced reactions) was the predominate loss mechanism for the remainder of the pesticides. The in-stream transformation rates are based on a review of literature data by Mackay *et al.* (1997). The pesticides were classified into seven transformation groups (Table I). The centre of the half-life range for each group was used in these calculations. Although transformation reactions were an important loss mechanism for all of these compounds, the calculated rate of transformation varied greatly among the pesticides. Malathion and propanil were estimated to have half-lives on the order of 1 to 2 days in the stream, whereas others (atrazine, lindane, and terbacil) were estimated to have half-lives on the order of 1 to 3 years.

Stream observations of LAPU

The results of the simple modelling of percent lost in a 15 day travel time (Table I) are in agreement with actual observations of LAPU in the streams. Metolachlor and trifluralin are used as examples of two types of behaviour in Figure 2. Metolachlor is used an example of those compounds that have minimal in-stream loss. Trifluralin is used as an example of those compounds that have substantial in-stream loss. All of the LAPUs for metolachlor and trifluralin, from both field runoff and stream observations, have been combined in Figure 2. There are 278 LAPU values for metolachlor and 105 LAPU values for trifluralin. Although, for a given watershed area, there is substantial variation in the log LAPU values for both metolachlor and trifluralin because of differences in rainfall or irrigation and terrestrial conditions (Capel and Larson, 2000), the overall relations between LAPU and watershed area are different for the two compounds. Metolachlor has the same range of LAPU values throughout the range of scale. On the basis of an ANOVA test, the mean LAPU values

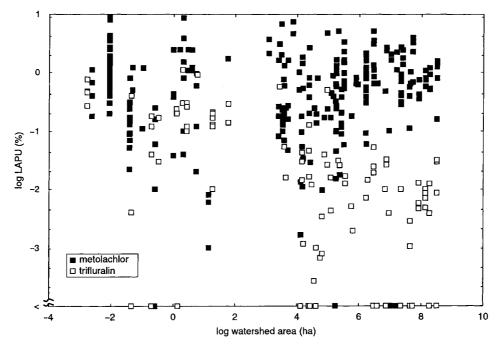


Figure 2. log LAPU (%) as a function of log watershed area (ha) for two herbicides, metolachlor and trifluralin. Data reported for watershed areas < log 2 ha are from field-based studies. Data reported for watershed areas > log 2 ha are from stream-based studies

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do not vary among field plots (<60 ha) and small ($<10^5$ ha), medium (10^5 to 10^7 ha), or large ($>10^7$ ha) watersheds (p=0.66). Also, the slope of the regression line of log LAPU versus log area is essentially zero (0.0033). These two observations suggest strongly that the LAPU values observed in field runoff are in the same range as the LAPU values determined from stream loads and that a minimal amount of metolachlor is lost through in-stream processes. The latter observation is consistent with the prediction reported in Table I. On the other hand, the trend in the LAPU values, as a function of watershed area, is different for trifluralin than for metolachlor. The field-scale ($<10^2$ ha) observations of log LAPU have little relation with log area, but are statistically different from the LAPUs observed in the streams (Table II, p < 0.001). The stream observations of LAPU show a trend of decreasing LAPUs with increasing watershed area (Table II). The trend in the observed LAPUs is consistent with the prediction reported in Table I of substantial loss of trifluralin from the stream due to volatilization.

On the basis of the observed LAPUs as a function of watershed area, the behaviour of the 39 pesticides quantified by the NASQAN and NAWQA program fall into three general groups. The first group consists of pesticides that were seldom seen in surface water (Table II). The compounds in this group have low-use amounts (lindane, permethrin, and pronamide, Table I), use only in limited geographical areas (DCPA, ethalfluralin, molinate, pebulate, and thiobencarb), short soil lifetimes (disulfoton, malathion, and parathion), short aquatic lifetimes (propanil and terbufos) and (or) use practices that diminish the chance of runoff, such as soil incorporation (benfluralin, napropamide, and terbufos) or application late in summer when little rain-producing runoff occurs (disulfoton and malathion). Not much information about the behaviour of these compounds can be gleaned from these data, except that their relative absence from the water can be explained, for the most part, on the basis of use, application practice, or relatively fast loss from soil and (or) water. Phorate is the one exception. It was not observed in any of the basins that meet the minimum use criteria, but has relatively high use (ranked 34th nationally in use), is commonly applied at the soil surface, and is estimated to have a relatively low in-stream loss rate (Table I). It is often applied in granular form, so it may not be as available for transport in runoff.

The second group includes those compounds that show little, if any, loss within the stream network. This can be quantified by comparing the LAPU values observed for streams draining smaller watersheds (<10⁵ ha) and LAPU values for larger watersheds (>10⁷ ha). Because the actual travel times of the pesticides in the streams are unknown, watershed area is used as a surrogate for travel time. Alachlor, atrazine, cyanazine, diazinon, metolachlor, metribuzin, propachlor, and simazine have mean stream LAPU values that differ by less than a factor of two, suggesting that there is relatively little in-stream loss of these compounds. This agrees very well with the results for the simple model predictions, which suggest that these eight compounds have relatively small in-stream losses (<37%) in a 15 day travel time (Table I). Three other compounds, predicted to have this same range of loss from surface water, are not included in this list of eight. These three are ethoprop, lindane, and terbacil. Lindane and terbacil have very low use amounts and are seldom detected in surface waters, so their losses cannot be explained using these data. Ethoprop meets the minimum use criteria in 16 studies, but only seven LAPU values could be calculated, which means that it was also observed infrequently in the streams. This may be due to a combination of relatively low use (ranked 67th in use) and a low potential for transport in runoff (median LAPU value: 0.0080% for watersheds > 100000 ha). It was observed at low concentrations in the small watersheds, but never quantified in the larger watersheds. This probably is due to dilution, yielding concentrations below the detection limit, rather than in-stream losses, but there is not enough data available to say this conclusively.

The third group consists of those compounds that have a difference in the mean LAPU values greater than a factor of two between the two watershed sizes. In all cases, the LAPU values for the larger watersheds are smaller than the LAPU values for the smaller watersheds. This suggests strongly that there is in-stream loss occurring for these compounds. Because these compounds were observed in the smaller watersheds, the pesticides did move off the fields and into the stream, but a substantial fraction (on average 50 to 100%) was lost during transport in the stream. This group of compounds includes azinphos-methyl, butylate,

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carbaryl, carbofuran, EPTC, ethoprop, fonofos, linuron, methyl parathion, pendimethalin, propargite, triallate, and trifluralin.

Another way to divide the selected pesticides is by type and application method: surface-applied herbicides, incorporated herbicides, and insecticides (Table I). On the basis of an ANOVA test, the surface-applied herbicides have significantly greater mean LAPU values in all three categories of watershed area ($<10^5$, 10^5-10^7 , and $>10^7$ ha, p<0.001 for all three) compared with the incorporated herbicides and insecticides. This is in agreement with the findings from the field runoff studies.

When the LAPU values are compared among the three categories of watershed area, the incorporated herbicides had significantly greater LAPU values in the small watersheds ($<10^5$ ha) than in the largest watersheds ($>10^7$ ha). This is in agreement with loss estimates reported in Table I, where all of the incorporated herbicides had estimated in-stream losses $\ge 70\%$, except for triallate. In contrast, there is no significant difference in the LAPUs for the surface-applied herbicides among the watershed area categories. This is also consistent with the model predictions. All seven surface-applied herbicides that were frequently observed (alachlor, atrazine, cyanazine, metolachlor, metribuzin, propachlor, and simazine) had estimated instream losses $\le 40\%$. Finally, there was also no significant difference in the LAPUs for the insecticides, even though the 16 insecticides included in this study have a wide range of estimated in-stream losses (14 to 99%).

Median small-scale LAPU values

The median small-scale LAPU is a measure of the central tendency of the LAPUs of an individual pesticide across a variety of environmental conditions and watershed areas (Table II). The variability around this central tendency is illustrated in Figure 3 for five example herbicides. The median small-scale LAPU is calculated as the median LAPU values for the field studies and the small watershed studies (<100 000 ha). Data from only field and small watershed studies (<100 000 ha) were used to minimize the bias from in-stream losses. A LAPU value of zero was substituted for any '<' in the calculation. Thiobencarb had no measurements of

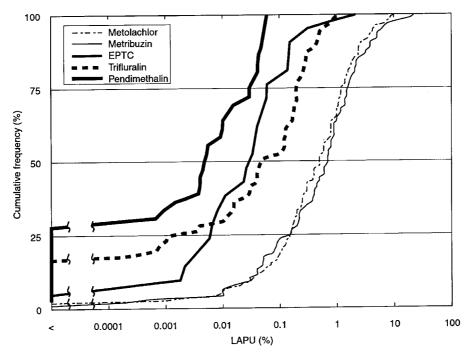


Figure 3. Cumulative frequency diagram of the LAPUs for five herbicides from studies of fields and study plots (<100 ha) and small watersheds (101-100 000 ha)

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LAPU in either fields or streams, so no median small-scale LAPU value is reported. Pronamide, propanil, and terbacil had only one watershed observation of LAPU, so was not included in the following discussion.

Three pesticides—DCPA, napropamide, and molinate—had median small-scale LAPU values greater than 1%. Because these three compounds had only a few measured LAPU values, their median small-scale values reported in Table II have a high degree of uncertainty. If the median small-scale LAPUs are ranked for the herbicides, the incorporated herbicides generally have smaller values, and the surface-applied herbicides the larger values. The mean LAPU values for the surface-applied herbicides, incorporated herbicides, and insecticides, are compared in Table II. The median of the median small-scale LAPUs is also much greater for the surface-applied herbicides (0.5%) than the incorporated herbicides (0.0031%). Pendimethalin, a surface-applied corn herbicide, has a much lower median small-scale LAPU compared with the other surface-applied herbicides. It also has a much greater tendency to sorb, as quantified by its log $K_{\rm oc}$ value (Table 1), than the other surface-applied herbicides. Because of the stronger sorption tendencies, the runoff of particles may control the extent of pendimethalin's runoff, whereas the runoff of water may control the extent of runoff of the other more water-soluble surface-applied herbicides.

DISCUSSION

Many factors influence the behaviour of a pesticide from the time of its application to an agricultural field to the time that it is delivered to the ocean. Figure 4 attempts to capture, in a generic manner, the range of behaviour across this range of scale. The axes of Figure 4 are the log of watershed area (to represent scale effects and riverine travel time) vs the log of LAPU. This allows both an easy compound-to-compound comparison and a watershed-to-watershed comparison for the same compound, because it normalizes for the amount of use. The vertical line in the figure represents the transition between agricultural field and first-order stream (or drainage ditch). This is the scale at which the pesticide runs off the field and enters the riverine network. The behaviour of five different generic pesticides, denoted A, B, C, D, and E, is plotted, and will be described individually. There are additional details drawn for compound 'A' that are applicable to the other compounds, but not included for the sake of simplicity.

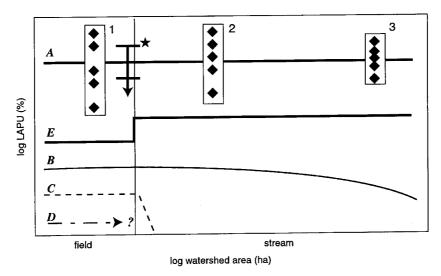


Figure 4. Cartoon of the apparent LAPU value of five generic pesticides (A–E) in their field runoff and surface water transport as a function of scale. Boxes 1–3 represent the year-to-year variability at a given site. The star represents the range of variability in the LAPU for the various terrestrial environments. The median small-scale LAPU for compounds B and C could be anywhere on the *y*-axis. This cartoon just demonstrates their relative in-stream behaviour. Based on field observations, the scale of the *y*-axis (log LAPU in percent) is generally between –4 and 1 (0·0001 and 10%)

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The median small-scale LAPU value for a given pesticide is partially controlled by the combination of its application method, formulation, and chemical properties (Capel and Larson, 2000). These three are somewhat interrelated. The variability around the median small-scale LAPU is due to the natural terrestrial environment (soil, slope, etc.) and the standard management practices (tillage, crop, etc.) for that pesticide. In Figure 4, the 'I-beam' at the star represents this variability around the median small-scale LAPU value. Capel and Larson (2000) showed that the median small-scale LAPU value for atrazine was 0.66% and that the central tendency was relatively constant from data collected in watersheds that ranged over 14 orders of magnitude in area. They also showed that part of the variability in the LAPU values for atrazine could be related to the extent of water yield during the period corresponding to the period of maximum atrazine runoff.

The arrow at the bottom of the 'I-beam' (Figure 4 at the star) represents the desired impact of BMPs on pesticide runoff. That is, the implementation of BMPs is supposed to reduce LAPU values. BMPs can be implemented through landscape modifications (i.e. vegetative buffer strips), conservation tillage methods, decreased use of pesticides, and (or) method of application. The first two groups of BMPs, although very important, would most likely decrease the median small-scale LAPU of water-soluble pesticides only slightly. The impact of these types of BMP would probably be measured as part of the inherent variability in the chemical's LAPU value. In Figure 4, this would have the effect of extending the lower portion of the 'I-beam'. On the other hand, decreased use or changes in the application method have the potential for a more significant impact. As an example, if the application method of a herbicide, such as atrazine, is changed from surface-applied to incorporated, its runoff behaviour might be characterized as changing from compound A to compound B in Figure 4.

The numbered boxes represent the year-to-year variability because of weather (or excess irrigation) that can be expected at different points in the range of scale (Capel and Larson, 2000). At the field scale (Figure 4, box 1), the variability is very high because of the influence of individual storms. As observed in many plot studies (Leonard, 1990), it is often the intensity and timing of rainfall with respect to application that determines the extent of runoff of the pesticide for any given year. This year-to-year variability decreases somewhat at the small watershed scale that integrates runoff from tens to hundreds of farm fields (Figure 4, box 2). There will still be years that are 'outliers', compared with the long-term average, caused by drought or very large storms that produce runoff for numerous fields at the wrong time with respect to pesticide application. This was observed with atrazine in the Sugar Creek watershed in Indiana (area: 24 600 ha), where the LAPU values for the 6 years 1993-1998 were 1.3%, 0.80%, 0.82%, 2.2%, 14%, and 2.3% respectively. The year that had a LAPU of 14% had an unexpected storm that came soon after the time of atrazine application (Capel and Larson, 2000). At the largest scale (major rivers, Figure 4, box 3), the year-to-year variability will be less, because of the integration of the runoff from thousands of agricultural fields over a very large area. The timing of application in these large watersheds for any given compound may vary by weeks because of climate differences. There seldom will be weather patterns that would affect the runoff in a large enough area to affect strongly the LAPU observed in the largest rivers.

The differences in the generalized behaviour of each of the representative compounds can be considered. Compound A has a relatively high LAPU value that is constant over the range of scale. This means that a substantial percentage of the amount applied is lost in runoff from the field and that there is little loss within the riverine network. This is the behaviour observed for atrazine, described in detail in Capel and Larson (2000), as well as metolachlor (Figure 2) and alachlor and cyanazine (Table II). The compounds in this group are the pesticides that are most frequently detected and exhibit seasonally elevated concentrations in rivers and streams over the complete range of scale (Larson *et al.*, 1999).

Compound B is representative of a pesticide that has moderate in-stream losses. Because the median small-scale LAPU is determined by the chemical, its formulation, and application method, it can fall anywhere in the range of median small-scale LAPU values. The difference in compound B, compared with compound A, is its accelerated rate of loss in the riverine system. Examples of compound B would be EPTC, trifluralin (Figure 2), and other pesticides in Table II that have losses in the range of 20 to 90% for the example 15 day travel time. These compounds are expected to be seen more frequently and at higher concentrations in small

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streams compared with the larger rivers. Because their observed LAPUs will decrease as a function of travel time in the river (Table 2), the extrapolation of stream observations back to field runoff must be done with great caution.

Compound C is similar to compound B, except that its riverine loss processes are much faster. Examples of these compounds include azinphos-methyl, ethalfluralin, malathion, pebulate, and terbufos (Table II). They are seldom detected in surface waters removed from direct agricultural runoff (Larson *et al.*, 1999).

Compound D is representative of those compounds that have very short lifetimes (days) in the soil that are seldom seen in field runoff, such as propachlor and propanil. These compounds are also seldom detected in surface waters (Larson *et al.*, 1999).

Finally, compound E is representative of those compounds that have incorrect (artificially high) LAPU values in watersheds. These pesticides, such as diazinon and simazine, have other substantial uses, in addition to agriculture, that act as sources to the environment. Because the LAPU value defined here is based on agricultural usage (Gianessi and Anderson, 1996), the LAPU value observed in some watersheds will be artificially high. In the USA, diazinon is often observed in surface waters in the Pacific coast states, in the Midwest, and in urban streams (Larson *et al.*, 1999; Hoffman *et al.*, 2000). Diazinon is frequently used in orchards in the West; therefore, some of the soil degradation processes could be by-passed in its transport from tree to stream. Diazinon also has wide-scale home and garden uses in urban areas. Larson *et al.* (1995) have suggested, on the basis of the temporal concentration patterns in the White, Ohio, and Mississippi Rivers, that the dominant source of diazinon to these rivers is urban rather than agricultural.

One goal of agricultural and regulatory managers is to reduce the amount of pesticides that get into, and are transported through, surface waters to minimize the potential impact on the biological community. On the basis of Figure 4, this can be achieved by decreasing the LAPU of current pesticides through BMPs, particularly the application method, or by creating new compounds that are quickly lost in the soil or water and, thus, have small LAPU values. Both of these methods are being used to reduce the load of pesticides in surface waters. Historically, there has been a move to less persistent pesticides (i.e. DDT to organophosphates). There also has been an increase of BMPs to control runoff (i.e. conservation tillage, buffer strips, and contour ploughing). The use of precision agriculture may be used to decrease the amounts of pesticides used on a field and decrease the pesticide load in runoff. Perhaps one of the simplest and most effective BMPs (based on the findings of this study) would be changing the method of application and formulation, when it is possible. There could be a substantial reduction in the amount of herbicides delivered to surface waters if there was a move away from surface application. Of course, such a change must balance considerations of efficacy, crop toxicity, and chemical properties against a decrease in the amount of the herbicide in runoff and the concomitant change in its impact on the health of aquatic ecosystems and humans, and the increased potential for the contamination of ground water.

A pesticide concentration or load in a given stream is the result of the combined processes that affect the extent of runoff and the extent of in-stream losses. To understand properly and characterize its behaviour, both of these sets of processes must be considered together. For atrazine, Capel and Larson (2000) showed that the observations of LAPU in streams across the complete spectrum of scale could be extrapolated back to the extent of field runoff. That is, the LAPU values measured in field runoff were not significantly different from those measured in streams. This same behaviour can be seen for metolachlor in Figure 2. In fact, all of the pesticide included in this study (with sufficient observations to evaluate) had the same range of LAPUs in the smallest streams as in field runoff studies. For many of these compounds, the observed LAPU decreased or went to zero in the larger streams. These observations point to three important components of pesticide behaviour that must be considered when interpreting monitoring data and making regulatory decisions. First, the results of field runoff studies are directly applicable to estimating the amounts of pesticides delivered to surface water systems. Second, many pesticides are lost within the surface water system, some quite quickly. Therefore, infrequent detection of individual pesticides in streams does not necessarily mean that they were not initially delivered from the field to the stream. Third, each pesticide is a different organic chemical and,

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thus, will behave uniquely with respect to its environmental transport, fate, and effect on human and ecosystem health

The concern over the occurrence of pesticides in surface waters is largely driven by their potential impacts on human and ecosystem health. In many ways, the concerns change as a function of stream size. In smaller streams, the focus of concern is on ecosystem health. Smaller streams make up the majority of riverine miles and provide important habitat for reproduction of aquatic organisms. There are relatively few public drinking water intakes on very small streams. The concern in larger streams and rivers focuses more on human health because they more commonly serve as sources of drinking water. The larger streams also tend to have numerous perturbations (industrial chemical inputs, thermal inputs, dredging, etc.) that have permanently changed the natural ecosystem. Although the impact of pesticides in large rivers may still be important, it is only one of many potential impacts on their ecosystems. (The exceptions to this are the persistent, organochlorine insecticides that readily bioaccumulate. They are of concern to both human and ecosystem health throughout the entire spectrum of watershed areas.) Given these changing concerns with stream size, it should be reiterated that each pesticide is a different organic chemical and, thus, will behave uniquely in its environmental transport, fate, and effect on human and ecosystem health. Only through detailed runoff studies and broad-scale stream monitoring, in conjunction with insights provided by process-based models, can the behaviour of individual pesticides be characterized to the extent that is needed to interpret monitoring results fully and make regulatory decisions.

ACKNOWLEDGEMENTS

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From: Pease, Anita

To: cathy.tortorici@noaa.gov

Cc:

Subject: EPA"s consolidated comments on the second ESA Report to Congress

Date: Monday, May 23, 2016 3:52:42 PM Attachments: **General Comments to Address.docx**

ESA Report to Congress Combined Comments EPA.docx

Cathy,

Please see attached EPA's consolidated general and specific comments on the second Report to Congress. Thanks.

Anita Pease **Acting Director** Environmental Fate and Effects Division U.S. EPA Office of Pesticide Programs 703-305-0392 pease.anita@epa.gov



From: Pease, Anita

To: gina shultz@fws.gov; Patrice Ashfield (patrice ashfield@fws.gov); cathy.tortorici@noaa.gov; Kunickis, Sheryl-

OSEC; Echeverria, Marietta; Dumas, Richard

Subject: EPA comments on Step 3 methods from FWS **Date:** Friday, February 24, 2017 9:52:44 AM

Attachments: 2017 0214 Integration and Synthesis Framework EPA comments.docx

20170215 Draft &S Summary karner bb rev wd EPA comments.docx 20170215 draft Scorecard Main MoapaDace rev wd EPA comments.docx

<u>Draft Interpretation of Mag Tool output for Karner Blue Butterfly 02 08 17 EPA comments.docx</u>

Plants Effects Framework 1-31-2017 EPA comments.docx Terrestrial effects framework 1-31-2017 EPA comments.docx

Hi folks,

This is the first of 2 emails transmitting EPA comment's on the Services' Step 3 methods and examples.

Attached are EPA's comments on FWS' methods including the following:

- Overarching I/S Framework
- Plant Effects Framework
- Terrestrial Effects Framework
- Scorecard and Magtool Output Interpretation for the Karner Blue Butterfly
- Scorecard for the Dace

The next email will transmit our comments on NMFS' methods and examples.

We'll look forward to seeing a revised agenda on Monday for the 2/28 meeting to discuss our comments. Thanks.

Anita Pease
Associate Director
Environmental Fate and Effects Division
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Pages 95-141 Deliberative process privilege – FOIA Exemption 5

From: Pease, Anita

Lewis, Susan; cathy.tortorici@noaa.qov; Kunickis, Sheryl - OSEC; gina shultz@fws.qov; Aubrey, Craiq; Patrice To:

Ashfield (patrice ashfield@fws.gov); Cowles, James

Goodis, Michael; Guilaran, Yu-Ting; Arrington, Linda; Sherman, Kelly; Perry, Tracy; Jakob, Avivah Cc:

Subject: ESA check-in

ESA STAKEHOLDER WORKSHOP (Charge Questions WOE Groups) 6 15 16.docx ESA STAKEHOLDER WORKSHOP (Charge Questions REFINEMENTS) 6 9 16.docx Attachments:

stakeholder wksp breakout sessions w charge questions 061416.docx

Dial in#: Code:

Agenda:

- ESA stakeholder workshop
- Agreement on charge questions!
- Draft BE comment period close
- BiOp schedule
- EPA sending exposure values to NMFS/FWS during the summer
- How goes it with comments on the draft BiOp timeline?
- Report to Congress
- Future BiOp planning group What is the deadline for the list, can we prioritize neonicotinoids, pyrethroids, and cholinesterase inhibitors on the list, and can we put the development of a programmatic consultations as the goal for out year planning
- Where are we with the RPA alternatives for the most recently signed BiOp?
- Planning for the meetings on June 27 28, 2016 it is underway!
- * Who is attending the workshop from NMFS.

ESA STAKEHOLDER WORKSHOP (JUNE 29 – 30, 2016):

Breakout Sessions WOE 1 and WOE 2: Weight of Evidence for Listed Animals and Plants

The draft biological evaluations for chlorpyrifos, diazinon and malathion rely upon a weight of evidence (WoE) approach to make species-specific effects determinations. Risk conclusions are based on the integration of exposure and effects information relevant to an individual of a listed species, as well as life history characteristics that may influence exposure or indirect effects (e.g., diet). Different types of effects are identified in this approach as separate lines of evidence; including: mortality, growth, reproduction, behavior, sensory effects and indirect effects. Additionally, other factors that could affect the magnitude of both direct and indirect effects (e.g., chemical or abiotic stressors) are evaluated as lines of evidence. Weighting is applied to each line of evidence and the weighting criteria provide guidelines for supporting effects determinations based on the pairings of risk and confidence. The current weighting criteria are defined in Attachment 1-9.

An effort was made to incorporate and evaluate as much toxicity and exposure data as possible to determine whether adverse effects are anticipated from the effects of the action. Both the toxicity and exposure information are evaluated to determine the risk and confidence associated with each line of evidence. Currently, the process uses numeric thresholds to determine risk. EPA and the services have discussed integrating distributions of effects and exposures to move towards a more probabilistic approach (e.g., such as the method used in the Terrestrial Investigation Model); however, this is seen as more of a long term goal for application to all species. EPA and the Services are interested in suggestions that improve the WoE method. When addressing the questions below, answers will be grouped into "short term" or "long term" solutions, considering the magnitude of work associated with developing and applying the methods to all listed species ($n \approx 1800$).

The same set of questions will be considered by the WoE groups focused on plants and on animals; however, the discussions are expected to differ. For instance, issues related to exposure differ between animals and plants in that the routes and models are conceptually and mathematically different. For effects, data are available for multiple lines of evidence for assessing direct effects to animals (i.e., mortality, growth, reproduction, behavior and sensory); whereas mortality, growth and reproduction data are only available for plants. It is expected that discussions related to animals will likely surround the topics of assessing direct effects to listed individuals as well as indirect effects due to impacts on animals and plants. For plants, discussions should probably focus more on indirect effects due to impacts to animals upon which they depend (e.g., for pollination or seed dispersal).

- Exposure Information Criteria used to assess exposure estimates ultimately answer the
 question, "how confident are we that exposure estimates represent environmental
 concentrations that could occur based on allowable labeled use?" The current approach for
 characterizing exposure considers the <u>relevance</u> of predicted EECs for species' habitats and the
 robustness of EECs derived from environmental fate models (see Attachment 1-9 for more
 details). Considering the current approach to characterizing exposure:
 - o **CHARGE QUESTION 1**: Comment on/suggest alternative methods for presenting exposure information (e.g., probability distributions, consideration of a range of exposure estimates, consideration of duration of exposure) and how the information can be weighed for each line of evidence's risk conclusion.
 - CHARGE QUESTION 2: Comment on the criteria used to weight Confidence in the estimation of exposure as described in Supplemental Information to Attachment 1-9.

- **Effects Information** Similar to the exposure characterization, the effects data are evaluated to answer the question, "how confident are we that available toxicity data will accurately predict an effect to the listed species?" The current approach considers 1) <u>biological relevance</u>- whether there is an established relationship between the measure of effect and the assessment endpoint, 2) <u>relevance of surrogate</u>- how representative the tested organisms used in the toxicity studies are at informing the potential for adverse effects to listed species or critical habitat, and 3) <u>robustness</u>- whether there is consistency within the line of evidence for the taxonomic grouping of interest (see Attachment 1-9 for more details). Considering the current approach to characterizing effects:
 - CHARGE QUESTION 3: Comment on approaches for incorporating data quality into the weight assigned to a line of evidence. The current approach to data quality is described in Attachment 1-8.
 - CHARGE QUESTION 4a: For animals, to what extent can taxa with robust data sets be used as surrogates for other taxonomic groupings where lines of evidence have little or no data (e.g., mammals for reptiles)?
 - CHARGE QUESTION 4b: For plants, comment on the approach to surrogacy. Is there a better or more representative way to group species?
 - CHARGE QUESTION 5: How can we more effectively incorporate the breadth of the available toxicity information (*i.e.*, not just the most sensitive endpoints), including magnitude of effect, into the characterization of effects and weight of evidence?
 - CHARGE QUESTION 6: How can we effectively weigh the impacts of other stressors (e.g., temperature) on the LAA/NLAA call, especially in the event of little or no data? CHARGE QUESTION 7: Are there additional sublethal effects that have an established relationship with an assessment endpoint that should be considered as lines of evidence?
 - CHARGE QUESTION 8: Comment on the criteria used to weight Confidence in the estimation of effects as described in Supplemental Information to Attachment 1-9.
- Risk Estimation- Risk is established by comparing the overlap of exposure with effect levels from available toxicity studies for each line of evidence. Consideration is given to the degree of overlap between exposure and effects data. Considering the current approach to estimating risk:
 - o **CHARGE QUESTION 9**: Comment on the criteria used to weight Risk as described in Supplemental Information to Attachment 1-9.

ESA STAKEHOLDER WORKSHOP (JUNE 29 – 30, 2016):

Breakout Session: Refinements to Steps 1 and 2 (Ideas for 'streamlining' and/or improving the analyses used to make effects determinations in future BEs)

In accordance with the Endangered Species Act (ESA), the Biological Evaluation (BE) determines whether there is a potential for a single individual of a listed species, or its designated critical habitat, to be adversely affected (directly or indirectly) by a federal agency's proposed action (in this case registering pesticide labels). This is accomplished by first identifying which species ranges/critical habitats overlap with the 'action area' (from the BE Step 1: 'May Affect'/'No Effect' determinations). Once a determination is made for each listed species and critical habitat, species- and critical habitat-specific analyses for all listed resources that have 'May Affect' determinations are conducted to evaluate whether there is a potential for a single individual (or essential critical habitat feature) to be adversely affected by the use of a pesticide (BE Step 2: 'Likely to Adversely Affect'/Not Likely to Adversely Affect' determinations). Therefore, Step 1 is intended to identify those species/critical habitats that require species-specific analyses (i.e., those that need to proceed to Step 2) and Step 2 is intended to identify the potential for adversely affecting a single individual or critical habitat feature. Key to these processes is the ability to identify areas of overlap among potential use sites, areas of potential effects, and species range/critical habitat areas over the duration of the proposed action (in some cases this may be 15 years or more).

- Breakout Group: REFINEMENTS 1 (Refinements to Steps 1 and 2: Spatial analysis):

O For agricultural uses, the interim process identifies potential use sites by collapsing >100 Cropland Data Layer (CDL) classes into 11 agricultural use categories, some of which are unambiguous major crops (corn, cotton, etc.), and some of which are aggregated "minor" crops, e.g., orchards and vineyards, or ground fruit and vegetables. (These minor crops were aggregated to address uncertainties in crop identification in the CDL, and to anticipate future use areas for pesticides, based on current uses.) Therefore, in some cases, specific crop uses are being identified in areas where the specific crop likely does not occur. For example, the orchard-vineyard layer is used for all orchard crops, including citrus. Diazinon is registered for some orchard crops, but not citrus – the spatial analysis is showing orchard use sites for diazinon in Florida – but most of those use sites are likely citrus.

1

¹ The action area is defined by statue as all areas to be affected directly or indirectly by the Federal Action and not merely the immediate area involved in the Action (50 CFR 402.02). The action area is, thus, related to the proposed action and is independent of the geographic area in which listed resources occur.

² Adverse effects to an individual are not limited to mortality, and include short-term and temporary effects (from direct and/or indirect effects) to individuals. Step 2 analyses do not evaluate the potential for "jeopardy" or "adverse destruction/modification" for species and critical habitat, respectively. Such an analysis would be conducted in Step 3 in a Biological Opinion.

- <u>CHARGE QUESTION 1a</u>: Is there a better way to accurately identify potential agricultural use sites, while still addressing concerns for future use for the duration of the proposed action?
 - Are there some CDL classes that we have more confidence in than others?
 - Is using the Census of Agriculture to eliminate counties where labeled uses do not occur a viable option for both current uses and future uses (within the duration of the proposed action)? If so,
 - O How should we deal with "undisclosed" census values?
 - O Do these data (or other suitable data) reflect "no usage" or "low" levels of usage over the duration of the proposed action?
- O Non-agricultural label uses include a wide range of land cover and land use categories. In the BEs, each label use is considered and represented by the best available land cover data. Generally, the National Land Cover Dataset (NLCD) is used to represent non-agricultural label uses. When the NLCD is inadequate, other data sources are used as appropriate.
 - <u>CHARGE QUESTION 2a</u>: Is there a better way to accurately identify potential non-agricultural use sites, while still addressing concerns for future use for the duration of the proposed action?
 - Are there additional data not considered in the BEs that may be useful for geographically identifying non-agricultural use sites?
 - Are there surrogate data (those that could be used to help inform potential use sites) that could be used for non-ag categories that we have not considered?
- O Some uses do not have clear geographic boundaries (*i.e.*, they are difficult to limit geographically via label language). For some chemicals, this can result in an action area that encompasses the entire US and its territories.
 - <u>CHARGE QUESTION 3a</u>: How can we better identify potential use sites for pesticide uses that do not have clear geographic boundaries? How could these potential use sites be better identified spatially?
 - Could a process to modify labels (to clarify potential use sites) be developed during the BE process? If so, what would that process look like?
 - o For example, when in the BE process would label clarifications be most useful? Could label modifications be in the form of a registrant commitment to modify a label as part of the final decision? How could Bulletins Live Two be best used in the process?

- For uses such as mosquito adulticide use, what other information could be pulled in to the analyses to help accurately limit the spatial extent (for example census information, or protected/managed lands) for the duration of the proposed action? Is there a human population density threshold where the cost of applying a pesticide would be too high?
- If it is not possible to geographically define a use site, can we geographically define where the pesticide isn't (or wont' be) applied that would provide spatial refinement (*i.e.*, it will not be applied to open water, or urban areas, *etc.*).
- O The range data currently available for listed species are geospatially represented using polygons and they are used in the BEs with the assumption that the species use all areas of their polygon equally throughout the year.
 - <u>CHARGE QUESTION 4a</u>: Are there methods available that would allow for a refined understanding of the distribution of individuals within the range polygons?
 - Are there methods that can be used to help identify areas of concern within a species' range to better estimate the likelihood of exposure – preferred habitat, distribution of individuals (do they cluster, are they territorial, min patches requirements for a home range, fragmentation indices)?
 - Is there biological information that could be used to help identify areas of the range where exposure is unlikely (e.g., due to elevation restrictions) or very likely (e.g., preferred habitat)?
 - How can the effects on timing be better captured (considering both direct and indirect effects)? For example, for direct effects, at the time of year when a pesticide can be applied, is the species there at that time (e.g., is it only there for part of the year because it is migratory?) or at a life-stage when exposure is or is not likely (e.g., is it at an egg stage, subterranean, or in diapause at that time)? What about the resources it depends on (indirect effects)?
 - Should less refined species ranges (e.g., county-level) be treated differently than those that are more refined [keeping in mind that in many cases a species range is not at a sub-county level for various reasons (e.g., no survey data on private lands, wide-ranging species)]? Is the precision of the analysis equal?
 - Can we incorporate this information to apply a weighting to the overlap analysis (see charge question 5a below)?
- O In the pilot BEs, any overlap of the action area with a species range or critical habitat is considered a 'May Affect'.

- CHARGE QUESTION 5a: Does the overlap approach used in the pilot BEs to determine a 'May Affect/No Effect' determination provide an adequate screening process (one that is protective but not unrealistically conservative)?
 - When conducting a GIS overlap analysis using datasets with different levels of resolution, what are methods that could be used to ensure that decisions are made based on the datasets' limits of precision (e.g., how can we best avoid 'false positives' and 'false negatives' in the overlap analyses when considering the limits of precision of the datasets used)?
 - Would using a weighting approach for the likelihood of an overlap be useful when making the Step 1 determinations (instead of using only an overlap of the species range/critical habitat and the action area)? For example, for agriculture uses could we incorporate the number of years a cell was classified as the crop in a weighting approach (while still accounting for the duration of the action)?
 - Are there approaches that could be used to screen out species from further analyses besides solely an overlap of the species range/critical habitat and the action area (e.g., if no Step 1 thresholds for plants are exceeded, can plants that are not biologically pollinated be considered 'No Effect', if no other indirect effects are anticipated)?
- Breakout Group: REFINEMENTS 2 (Refinements to Steps 1 and 2: Non-spatial analysis):
 - O There are a multitude of use patterns on currently registered labels, some which result in potentially higher exposures to non-target organisms than others. For example, although somewhat dependent on chemical fate properties, pesticides applied to large agricultural fields by air are expected to result in higher offsite exposure than pesticides applied to a small area via a ready-to-use spray can.
 - CHARGE QUESTION 1b: Is there a way to identify use patterns that would result in minimal exposures, such as spot treatments, that may not always need to be fully re-assessed for each pesticide going through the consultation process (i.e., by applying what we have learned from an analysis with another pesticide with a similar use pattern)?
 - What type of things regarding the pesticide and use site would need to be considered [e.g., the fate properties of the pesticide, the amount of pesticide applied (e.g., per the label and/or based on usage information), the application method used, potential application sites (e.g., ready-to-use spray can)]?
 - Of these fate properties, how could they be considered keeping in mind use site parameters?
 - Of these use site parameters, how could they be considered (*e.g.*, personal ready-to-use spray can for mosquitos)?

- O There are a subset of listed species that are found in places or environments not expected to result in appreciable exposure to most pesticides (those that are not persistent and do not bioaccumulate) (e.g., species that live wholly or primarily in the open ocean, species only found on non-inhabited islands, and species found only in the arctic regions of Alaska).
 - CHARGE QUESTION 2b: Is there a way to identify species that may not always need to be fully re-assessed for each pesticide going through the consultation process (i.e., by applying what we have learned from an analysis with another pesticides)?
 - Once a species characteristics (e.g., habitat) has been considered, what type of things regarding the fate properties of the pesticide would need to be considered (e.g., aquatic half-life, mobility, bioaccumulation potential, etc.)?
 - Of these fate properties, how could they be considered (e.g., a full assessment might not be needed for pesticides that have a log K_{ow} <4)?
 - What types of biological/ecological attributes of the species would need to be considered (*e.g.*, its habitat)?
 - Of these species characteristics, how can they be considered (this may be different for species and designated critical habitats) (e.g., a full assessment might not be needed for species that live wholly or primarily in the open ocean, species only found on non-inhabited islands, and species found only in the arctic regions of Alaska, not present during windows of application; this may not apply to designated)?
- O The pilot BE process relies on thresholds for mortality that are based on probabilistic effects endpoints (e.g., 1-in-a-million chance of mortality based on the HC₀₅ of a SSD or the lowest LC₅₀/LD₅₀ values) compared to deterministic estimated environmental concentrations (EECs) (e.g., 1-in-15 year peak EEC value). Additionally, sublethal thresholds are assessed using deterministic sublethal thresholds (e.g., NOAECs or LOAECs) and deterministic estimated environmental concentrations (EECs) (e.g., 1-in-15 year peak EEC value). The current approach in the BEs is comparing an exposure value to a threshold for possible exceedances [similar to a risk quotient approach (i.e., exposure/effect)].
 - <u>CHARGE QUESTION 3b</u>: Is there a way to utilize the thresholds that is more informative (for example, in the weight of evidence) and goes beyond a deterministic approach (moving towards a more probabilistic approach for assessing risks as recommended by NAS)?
 - How could joint probability distributions of effects (the thresholds) and exposures (the EECs) be used to help inform the potential for risk?
 - Are there other probabilistic approaches that can help better inform risk at the individual and field levels?

- When making a "May Affect/No effect' determination, what are some practicable methods to better determine where both direct and indirect effects are either 'no effect' or 'discountable' (extremely unlikely to occur)?
 - O For example, could an action be "discountable" for certain species (*e.g.*, when there is no direct exposure or effects expected and no or insignificant/discountable effects to prey, pollinators, *etc.*).
- CHARGE QUESTION 4b: Is there an efficient way to incorporate exposure durations into the analysis of potential effects?
 - The pilot BEs currently compare all effects thresholds to peak EEC values. How can other durations of potential exposure be utilized and related to available toxicity studies (which are conducted under a range of exposure durations)?
 - Are there factors, other than duration, that should be considered when comparing the effects data to the EECs?

Estimating Exposure in Aquatic Habitats Represented by Flowing Bins 3 and 4

In the draft Biological Evaluations (BEs), effect determinations are made at the individual scale of biological organization. Consequently, the goal is to accurately predict maximum pesticide concentrations that may occur in different aquatic habitats utilized by listed species and are spatially and temporally relevant to the listed species. The modeling approach presented in the draft BEs leveraged EPA's current generic aquatic modeling approach by using the Pesticide in Water Calculator (PWC) shell, a combination of field-scale models (PRZM5/VVWM), to generate estimated exposure concentrations (EECs) for three generic flowing water bins of varying volumes and flow rates (Bins 2, 3, and 4). The Bin 2 estimates are intended to represent lower-flow habitats, such as first-order streams. When considered in relation to field-scale monitoring data, such as those obtained from edge-of-field (EOF) studies, model results should provide confidence in EECs for this bin. There is expected to be less confidence in applying this approach for deriving estimates for Bins 3 and 4, because processes that affect larger-scale concentration dynamics (e.g., longitudinal dispersion) are not accounted for. The EECs derived for these higher-flow habitats in the draft BEs are extremely high and seem to defy both professional judgement and typical patterns seen in contaminant monitoring data.

In the context of watershed hydrodynamics, the three flowing bins represent aquatic habitats which would ideally be representative, for example, of streams that are sequentially connected within a watershed. While runoff and drift from a field adjacent to a Bin 3 and/or 4 waterbody can directly contribute loading, the EECs generated from these types of events are being characterized with Bin 2 EECs, as these EECs may be reflective of concentrations occurring before complete mixing within the Bin 3 and/or 4 waterbody had occurred. Initial modeling generated Bin 3 and 4 EECs that exceed those generated for Bin 2, which runs counter to expectations based on standard transport dynamics, *e.g.*, dispersive dampening of chemographic peak maxima as a pulse of contaminant moves downstream. Given the apparently unreasonably high EECs for Bins 3 and 4, a qualitative approach was considered in the draft BEs for use in assessing these bins. The approach relied on monitoring data to demonstrate a downward trend in the magnitude of peak exposures. Consistent with published studies showing a reduction in exposures as one moves down a watershed network, the approach showed a 5-fold reduction in exposure from Bin 3-like streams and a 10-fold reduction from Bin 3-like streams to Bin 4-like streams. The draft BE also applied a qualitative comparison of volumes and flowrates to suggest a reasonably conservative magnitude of exposure expected in Bins 3 and 4 as a separate line of evidence.

Charge Questions:

- 1. EPA explored several factors in using the PWC, including incorporation of a baseflow and use of the daily average instead of the instantaneous peak EEC. What are the strengths and weaknesses of these modifications? Are there other modifications that can be made and what are their strengths and weaknesses?
- 2. How appropriate are the methods used in the draft BEs to develop field/watershed sizes and waterbody lengths for these Bins? What reasonable alternatives could be used to model watershed processes that allow for accurate estimation of possible exposure concentrations (including the maximum) in these flowing bins based on product labeling?
- 3. For the bins (3 and 4) that represent larger flowing systems, what ways of incorporating the effects of dispersive mixing and/or peak desynchronization into concentration estimates are reasonable?

- 4. What are the strengths and weaknesses of alternative mechanistic or regression-based watershed models such as the Soil and Watershed Assessment Tool (SWAT), the Hydrological Simulation Program-Fortran (HSPF) and the Watershed Regressions for Pesticides (WARP) for simulating aquatic pesticide concentrations at the temporal resolution and national scales required for ESA assessment? Are there other watershed models that should be considered?
- 5. What is the desired and appropriate spatial scale for EECs for Bins 3 and 4? Specific PWC EECs were developed for HUC2 regions. Can or should the EECs for Bins 3 and 4 be at a finer spatial scale given a nationwide consultation?

Evaluation of Aquatic Exposure Modeling Estimates

In the Draft BEs, EPA employed an approach for flowing waters in an effort to approximate watershed processes. Regardless of the model employed, the EECs from any model need to be conservative (*i.e.*, protective of the species of concern) and scientifically defensible in order to be used for risk assessment purposes. Typically, for EPA's use of PRZM5/VVWM as a field-scale model for vulnerable waters (*e.g.*, headwater streams), this would be done by comparing model outputs to field monitoring data (*i.e.*, edge of field runoff studies), where pesticide monitoring data is associated with pesticide-applications under well-described conditions (*i.e.*, application rates, field characteristics, water characteristics, and meteorological conditions). However, for watershed modeling, which aggregates exposure across a larger area, field-scale monitoring data, and the associated well-described conditions for all locations in the watershed, can be extremely difficult to obtain and, as a watershed model aggregates exposure, it may not be necessary.

Available literature documents have evaluated watershed models, including the NAS-recommended model SWAT, using general and targeted watershed monitoring data that is focused on known high pesticide-use areas, provided the data are collected at a high enough frequency to adequately capture the peak exposure concentration along with variations in concentration in the receiving stream. Unlike field monitoring data, general monitoring data (*i.e.*, sometimes described as ambient monitoring data) often lacks background information on application rates and field conditions and can be problematic when used for comparisons to model-generated EECs. They may, however, provide a lower bound for model-generated EECs. Targeted watershed monitoring (*e.g.*, studies at a watershed scale that are targeted to areas of known high pesticide use, with a sampling frequency targeted to the timing of use and subsequent runoff events) has been proposed as a means to provide more than a lower bound, especially when such monitoring spans multiple years and can be tied to factors that drive pesticide transport from field to water bodies. Such data are used to complement the results from modeling, not as a substitute for modeling.

In the Exposure chapter of the 2013 NAS report¹, the NAS noted that "If pesticides are to be used without jeopardizing the survival of listed species and their habitats, the estimated environmental concentrations (EECs) to which the organisms and their habitats will be exposed need to be determined. Chemical fate and transport models are the chief tools used to accomplish that task." (p. 49) The NAS further went on to describe a stepwise approach to fate and transport modeling, commenting on the use of various models such as AgDRIFT, PRZM, and EXAMS (p. 52-54). The NAS then cautioned that "in evaluating models, general monitoring data and field studies need to be distinguished. General monitoring studies provide information on pesticide concentrations in surface water or ground water on the basis of monitoring of specific locations at specific times. The monitoring reports, however, are not associated with specific applications of pesticides under well-described conditions, such as application rate, field characteristics, water characteristics, and meteorological conditions. General monitoring data cannot be used to estimate pesticide concentrations after a pesticide application or to evaluate the performance of fate and transport models." (p. 54) Though not as abundant as general monitoring data, field-scale monitoring studies are available for many pesticides, including the three OPs. However, monitoring data with this type of supporting information are generally lacking at the watershed scale.

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¹ National Academy of Sciences. 2013. Assessing Risks to Endangered and Threatened Species from Pesticides. The National Academies Press. Washington, DC.

Additionally, the general monitoring data, specifically at the watershed scale, sometimes include data sets which are spatially and temporally targeted to varying degrees with pesticide applications. Lastly, the NAS noted that "pesticide fate and transport models do not provide information on the watershed scale; they are intended only to predict pesticide concentrations in bodies of water at the edge of a field on which a pesticide was applied." (p. 54) The NAS also noted that "different hydrodynamic models are required to predict how pesticide loadings immediately below a field are propagated through a watershed or how inputs from multiple fields (or multiple applications) aggregate throughout a watershed." The NAS report did not provide additional discussion on the monitoring data requirements (e.g., metadata such as use rates, location, and timing) needed to evaluate watershed models.

Given the distinctions above between field-scale and watershed-scale models, the question arises "how does one evaluate the results generated from a watershed model?" EPA is proposing to use of the following multiple lines of evidence to evaluate the range of scientifically-defensible EECs for each flowing bin: consideration of available edge-of-field monitoring data and edge-of-field modeled estimates from PRZM5; incorporation of results from multiple watershed models, as appropriate; and consideration of statistical approaches to estimate confidence bounds around general monitoring data that were collected at a greater than a daily time step (*i.e.*, SEAWAVE Q and bias factors).

Charge Questions:

- 1. In what ways are a "multiple lines of evidence" approach appropriate for evaluating the results from a watershed model? What would be the "lines of evidence" and sources of information?
- 2. How can different types of monitoring data be distinguished? What metadata requirements (e.g., use info, sample frequency, etc.) can be used to distinguish types of monitoring data?
- 3. What roles can the various types of monitoring data play in the evaluation of results from a watershed model (e.g., general monitoring doesn't predict maximum but has other roles)?
- 4. What other approaches are available for evaluating results from watershed models?
- 5. To what extent can we rely on historical monitoring data when product labeling has changed and application-specific information is lacking?
- 6. Are there new or different types of monitoring that could be employed to further our understanding of aquatic modeling estimates?

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Goodis, Michael; Guilaran, Yu-Ting Cc:

Subject: ESA check-in

Dial in#: Code:

- Update on draft BEs
 Actions from 2/19/16 meeting
 Comments on CLA recommendations
 Subgroups to work on options for Decision Framework, revisions to Step 1 and 2 thresholds
- Next steps on pesticide consultation schedule planning ESA stakeholder meeting Status call with CBD and intervenors

- Report to Congress